Atomic Energy Control Board
P.O. Box 1046
Ottawa, Canada
K1P 5S9

Commission de contrôle de l'énergie atomique
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TRITIUM RELEASES FROM THE PICKERING NUCLEAR GENERATING STATION AND BIRTH DEFECTS AND INFANT MORTALITY IN NEARBY COMMUNITIES 1971-1988

(AECB Project No. 7.156.1)

by

Kenneth C. Johnson
Jocelyn Rouleau

Birth Defects and Poisonings Section
Diseases of Infants and Children Division
Bureau of Chronic Disease Epidemiology
Laboratory Centre for Disease Control
Health Protection Branch
Health and Welfare Canada

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TRITIUM RELEASES FROM THE PICKERING NUCLEAR GENERATING STATION AND BIRTH DEFECTS AND INFANT MORTALITY IN NEARBY COMMUNITIES 1971–1988

A report Kenneth Johnson and Jocelyn Rouleau, Health and Welfare Canada, with the assistance of Dr. Greg J. Sherman, under contract to the Atomic Energy Control Board.

EXECUTIVE SUMMARY

1) Background:

A recent study by a private citizen in Toronto alleged an association between deaths from congenial anomalies in the Town of Pickering and tritium releases from the Pickering Nuclear Generating Station. An association between tritium release and neonatal infant death was also described. External review by the Ontario Ministry of Health suggested the study had serious data and analytic shortcomings. The Atomic Energy Control Board decided (AECB) it would be in the public interest to have a thorough and independent analysis of the birth defect and infant death data undertaken. Accordingly, the AECB commissioned the Laboratory Centre for Disease Control, which runs the Canadian Congenital Anomalies Surveillance System, to examine more closely the risks of selected reproductive outcomes in the area and to examine whether the risk of any of these outcomes correlated with rates of tritium release from the power plant.

2) Objectives:

The first study objective was to examine whether there were elevated rates of stillbirth, birth defects, or death in the first year of life, between 1971 and 1988, among offspring of residents of communities in close proximity to the Pickering Nuclear Generating Station (within a 25-kilometre radius). The second study objective was to investigate whether there were any statistical associations between the monthly airborne or waterborne tritium emissions from the Pickering Nuclear Generating Station and the rates of these reproductive outcomes.

It was not the objective of this study to estimate radiation exposure levels for women living in the vicinity of the plant, nor to examine the plausibility or possible biological mechanisms by which *in utero* radiation exposure might occur.

The ecological design of this epidemiologic study imposes the same limitations on interpretation inherent to all studies of this design. The study deals with exposure at the level of communities, as opposed to the individual. Accordingly, the study can only identify associations at the level of the community—associations which may not hold for individuals. Furthermore, association is only one tenet of the detailed evidence required to male a causal judgement.

3) Data Source:

The AECB provided data to the Laboratory Centre for Disease Control, supplied via Ontario Hydro's effluent monitoring programme, on monthly airborne and waterborne releases of radioactive materials from the Pickering Nuclear Generating Station between 1971 and 1988. In addition, composite monthly data on airborne concentrations of tritium from five Health and Welfare and six Ontario Hydro environmental ground monitoring stations located one or two kilometres from the plant were made available after a preliminary analysis of release data had been reported.

Data on the prevalence at birth of birth defects, reported in the first year of life, were available for the period 1973-1988 from the Canadian Congenital Anomalies Surveillance System. Data on stillbirths and deaths during the first year of life between 1971 and 1988 were selected from summary files of Vital Statistics compiled by Statistics Canada.

4) **Analysis and Results:**

The data were analyzed for each of the six municipalities within the 25 kilometre radius, with attention focused on Pickering and Ajax, the two municipalities closest to the nuclear plant. The analysis had three major phases:

- a general screening of stillbirth, infant death and fatal birth defect rates by year and summarized over 1971-1988;

- an examination of birth prevalences of birth defects within three major categories in relation to airborne and waterborne tritium emissions and in relation to ground-monitored airborne tritium concentrations during the period approximating the first trimesters of these pregnancies; and

- a screening of the 1973-1988 summary birth prevalences of specific birth defects in the communities of Ajax and Pickering, followed by an analysis of the relationship to tritium release and ground monitored levels for those defects with statistically elevated birth prevalences.

In the first phase, standardized mortality ratios were calculated for each outcome, for each of the six study municipalities by year and for the whole study period. Outcome rates for the entire province of Ontario were used for comparison throughout the study. The rates of stillbirth, neonatal mortality and infant mortality were not significantly elevated for the period 1971-1988 in any of the study areas in comparison to the rates for the entire province. The rates of central nervous system (CNS) defects, congenital heart defects and a group comprising the balance of defects were not unexpectedly high between 1973 and 1988 in any of the six study areas. The analysis did not turn up any statistically elevated or unexpectedly high rates. In fact, the rates were generally lower than for the province, sometimes significantly so.

In the second phase, average and high monthly airborne and waterborne tritium emissions over a four month period were categorized into 5 levels. Births, CNS defects, congenital heart defects, and the balance of defects were also categorized by month and year of birth in each study municipality. Emission levels were assigned to each month and year of birth after moving them forward 9 months so that births occurring in the normal range of gestation would be assigned a tritium level approximating the tritium level during the first trimester of pregnancy. Birth defect rates were then calculated for each emission level and relative risks computed, comparing rates within each emission level to the lowest emission category.

A similar analysis was performed for Pickering using data from the three Health and Welfare Canada ground monitoring stations in the direction of Pickering on the periphery of the nuclear plant and for Ajax using the two stations in the direction of Ajax.

The only association between release levels and the three defect groups was between CNS defects in Pickering and the highest 12.5% of airborne tritium releases. However, the association could not be reproduced for the Pickering ground monitoring data; neither microcephaly (known to be related to ionising radiation exposure in the Atomic bomb studies) nor any other specific CNS defect was particularly high; and the overall birth prevalence of CNS defects for 1973-1988 was 20 percent lower for Pickering than for Ontario as a whole. No associations were found between higher ground monitoring levels and the birth prevalence of the three defect groups.

In the third phase, birth defects in Pickering and Ajax were divided into 22 diagnostic categories and analyzed. For those categories with statistically elevated standardized birth prevalence ratios, relative risk analyses were undertaken as above to observe whether there were any relationships to tritium levels.

In Pickering, only Down Syndrome birth prevalence was significantly elevated (maternal age-adjusted birth prevalence ratio 1.85, 95% confidence interval 1.19-2.76). A nonsignificant correlation was found between airborne tritium release levels and the Pickering Down Syndrome cases, but no correlation was found between Down Syndrome and the ground monitoring data. In Ajax, no anomalies had significantly elevated birth prevalence ratios, but Down Syndrome risk was elevated (although not statistically significantly so, maternal age adjusted risk ratio 1.46, 95% confidence interval 0.80-2.44). An association that was not statistically significant was found with the highest ground monitored tritium levels but there was no association with tritium emission levels.

5) Conclusions:

Overall, this analysis does not support a hypothesis of increased rates of stillbirths, neonatal mortality or infant mortality in the vicinity of the Pickering Nuclear Generating Station. Since the plant's start up in 1971, the rates of these conditions were neither high overall, nor were the patterns of yearly rates unexpected among any of the communities in the vicinity of the plant. Furthermore, the analysis does not support a hypothesis of increased birth prevalence of birth defects in the vicinity of the Pickering Nuclear Generating Station for 21 of the 22 diagnostic categories into which birth defects were divided for analysis.

The birth prevalence of Down Syndrome was elevated in both Pickering and Ajax, however interpretation of this elevated risk must be very cautious. There was no consistent pattern between tritium release levels and Down Syndrome birth prevalence, chance could not be ruled out for the associations between Down Syndrome and tritium releases or ground monitored concentrations, the association was detected in an analysis where multiple testing was done

which may readily turn up significant associations by chance, maternal residence at birth for Down Syndrome mothers in Pickering and Ajax needs to be verified, and we have no information about place of residence early in pregnancy. Furthermore, the association between Down Syndrome and low level radiation remains indeterminate when the existing evidence from epidemiologic studies is summed. Finally, the estimated radiation exposure from the nuclear plant for residents of Pickering and Ajax is lower by a factor of 100 than the normal level of natural background radiation.

Nevertheless, it would seem prudent to do further investigation of Down Syndrome in Pickering and Ajax. The first step would be to examine hospital charts to confirm maternal residence at birth and the Down Syndrome diagnosis and to establish the length of gestation for the 38 Down Syndrome cases. If the residences are confirmed and permission can be obtained from the Ontario Ministry of Health, HMRI, and the hospitals involved, we recommend a case-referent study be initiated. The case group would consist of the 38 Down Syndrome children born between 1973 and 1988 to mothers resident in Pickering or Ajax at the time of birth. A referent (comparison) group would be compiled by selecting births from Pickering and Ajax matched on birth year and born to mothers with similar maternal ages. The study would establish maternal residence during and before pregnancy, possible exposure to other radiation before and during pregnancy (e.g. x-rays) and information on other potential confounders such as mother's and father's occupation. An attempt should be made to obtain results of chromosomal tests that may have been done for some of the Down's cases. Newly arisen trisomies might then be separated from those that were transmitted (the translocations), providing a better indication of the etiology underlying the cases.

The study has primarily addressed public health as opposed to etiologic issues. We have tried to answer two questions:

a) Are there excess rates of specific reproductive outcomes in any of the municipalities in the vicinity of the Pickering NGS, overall or in specific years? and

b) Are there any associations between the levels of tritium releases from the plant and the rates of specific reproductive outcomes?

The attempt to answer these questions has required screening a variety of adverse reproductive outcomes for elevated risk over a series of years, in a number of municipalities. Some statistically significant associations are a likely outcome when many statistical tests are done. Therefore, such a screening process must be viewed as a hypothesis-generating exercise and the potential for significant associations by chance alone should not be underestimated.

SOMMAIRE

1) Historique :

D'après la récente étude publiée par un citoyen de Toronto, il serait possible d'établir un lien entre certains décès dus à des anomalies congénitales recensés dans la ville de Pickering et les rejets de tritium provenant de la centrale nucléaire de l'endroit. L'étude faisait aussi état d'un lien possible entre les rejets de tritium et les cas de mortalité néo-natale. Un examen indépendant du ministère de la Santé de l'Ontario a révélé que l'étude était basée suir des données sérieuses, mais que l'analyse comportait aussi des lacunes. La Commission de contrôle de l'énergie atomique (CCEA) a décidé d'entreprendre, dans l'intérêt public, une analyse approfondie indépendante des données sur les malformations congénitales et les cas de mortalité infantile. Elle a donc demandé au Laboratoire de lutte contre la maladie qui administre le Système canadien de surveillance des anomalies congénitales d'examiner plus attentivement le risque de certains effets sur la reproduction dans la région et de découvrir si le risque de l'un quelconque de ces effets pouvait être mis en corrélation avec les débits de rejet de tritium de la centrale nucléaire.

2) Objectifs :

L'étude visait d'abord à déterminer si les taux de mortinatalité, de malformation congénitale et de mortalité d'enfants de moins d'un an entre 1971 et 1988 étaient élevés parmi les enfants des habitants des agglomérations situées dans un rayon de 25 kilomètres de la centrale nucléaire Pickering. L'étude visait ensuite à établir s'il y avait des rapports statistiques possibles entre les rejets mensuels de tritium dans l'air et dans l'eau provenant de la centrale nucléaire Pickering et le taux d'anomalies.

En revanche, l'étude n'avait pas pour but d'estimer le niveau de radioexposition des femmes vivant à proximité de la centrale, pas plus que d'évaluer s'il était plausible que des fœtus soient exposés aux rayonnements et par quels mécanismes biologiques ils pouvaient l'être.

La conception écologique de la présente étude épidémiologique impose les mêmes limites à l'interprétation comme c'est le cas pour toute étude de ce type. Comme l'étude traite uniquement des irradiations des collectivités et non des individus, elle ne peut établir des liens qu'au niveau des collectivités et ces liens ne s'appliquent pas nécessairement aux individus. De plus, tout lien ne représente qu'un élément des preuves détaillées qui sont nécessaires pour établir une relation de cause à effet.

3) Sources de données :

La CCEA a fourni des données au Laboratoire de lutte contre la maladie à partir du programme de surveillance des effluents d'Ontario Hydro sur les rejets de matières radioactives dans l'air et dans l'eau provenant de la centrale nucléaire Pickering entre 1971 et 1988. En outre, des données mensuelles composites sur les concentrations de tritium dans l'air provenant de cinq postes de contrôle au sol de l'environnement de Santé et Bien-être social Canada et de six d'Ontario Hydro, situés entre un et deux kilomètres de la centrale ont été obtenues après qu'une analyse préliminaire des données sur les rejets eut été publiée.

Les données sur la fréquence de malformations congénitales à la naissance, rapportées durant la première année de vie, étaient disponibles de 1973 à 1988 à partir du Système canadien de

surveillance des anomalies congénitales. Les données sur les cas de mortinatalité et de décès d'enfants de moins d'un an entre 1971 et 1988 ont été choisis à partir de dossiers récapitulatifs des Statistiques de l'état civil de Statistique Canada.

4) **Analyse et résultats :**

Les données des six municipalités situées dans un rayon de 25 kilomètres ont été analysées et une attention particulière a été portée aux villes de Pickering et d'Ajax qui sont les plus rapprochées de la centrale. L'analyse comprenait trois étapes :

- une évaluation générale des taux de mortinatalité, de mortalité infantile et de malformations congénitales fatales par année et par bilan cumulatif entre 1971 et 1988;

- un examen de la fréquence à la naissance de trois catégories importantes de malformations congénitales, relativement aux rejets de tritium dans l'air et dans l'eau et aux concentrations de tritium dans l'air enregistrées au sol durant la période équivalant environ aux premiers trimestres des grossesses pertinentes;

- une évaluation de l'ensemble des cas de certaines malformations congénitales à la naissance observées entre 1973 et 1988 dans les villes d'Ajax et de Pickering, suivie d'une analyse du rapport entre, d'une part, les rejets de tritium et les niveaux enregistrés au sol, et d'autre part, les malformations dont la fréquence est élevée à la naissance.

Durant la première étape, on a calculé des ratios standardisés de mortalité pour chaque anomalie dans chacune des six municipalités, par année et pour l'ensemble de la période visée. On s'est servi des taux d'anomalies de toute la province de l'Ontario à des fins de comparaison tout au long de l'étude. Les taux de mortinatalité, de mortalité néo-natale et de mortalité infantile n'étaient pas particulièrement élevés entre 1971 et 1988 dans aucune des agglomérations visées comparativement aux taux de la province. Les taux d'anomalies du système nerveux central, de cardiopathie congénitale et d'un groupe comprenant les autres anomalies n'étaient pas plus élevés que l'on ne s'y attendait entre 1973 et 1988 dans chacune des six agglomérations. L'analyse n'a révélé aucun taux statistiquement élevé ou plus élevé que prévu. En fait, les taux étaient généralement inférieurs et souvent très inférieurs aux taux de la province.

Durant la deuxième étape, les rejets moyens et élevés de tritium dans l'air et dans l'eau pendant quatre mois ont été divisés en cinq niveaux. Les naissances, les anomalies du système nerveux central, les cardiopathies congénitales et les autres anomalies ont aussi été catégorisées par mois et par année de naissance dans chaque municipalité. Des niveaux de rejet ont été assignés à chaque mois et année de naissance, après avoir été avancés de neuf mois, pour que l'on puisse attribuer aux naissances se produisant dans les délais prévus de la gestation un niveau de tritium égal environ au niveau de tritium durant le premier trimestre de la grossesse. On a ensuite calculé le taux de malformations congénitales pour chaque niveau de rejet et le risque relatif correspondant, tout en comparant les taux de chaque rejet à la catégorie de rejet la plus faible.

Une analyse semblable a été effectuée pour la ville de Pickering à l'aide des données obtenues à partir de trois postes de contrôles au sol de Santé et Bien-être Canada dans la direction de Pickering à la périphérie de la centrale nucléaire et pour la ville d'Ajax à partir de deux postes en direction d'Ajax.

Le seul lien observé entre les niveaux de rejet et les trois groupes de malformations existait entre les anomalies du système nerveux central à Pickering et la classe des rejets atmosphériques les plus importants, soit 12,5 % de l'ensemble des rejets. Toutefois, ce lien n'a pu être reproduit pour les données de Pickering obtenues à partir des postes de contrôle au sol; les cas de micro-céphalie (dont on sait qu'ils peuvent être causés par les rayonnements ionsiants selon les études portant sur les survivants de la bombe atomique) ou de certaines autres anomalies du système nerveux central n'étaient pas élevés et, en général, les cas d'anomalies du système nerveux central à la naissance entre 1973 et 1988 à Pickering étaient 20 pour 100 inférieurs à la moyenne de l'Ontario. Aucun lien n'a pu être établi entre les niveaux plus élevés enregistrés par les postes de contrôle au sol et les cas des trois groupes de malformations à la naissance.

Durant la troisième étape, les malformations congénitales à la naissance recensées à Pickering et à Ajax ont été divisées en 22 catégories diagnostiques, puis analysées. Dans le cas des catégories dont les ratios standardisés de cas d'anomalies à la naissance étaient statistiquement élevés, des analyses de risque relatif semblables à celles qui ont été mentionnées plus haut ont été entreprises pour déterminer s'il existait des rapports possibles avec les niveaux de tritium.

À Pickering, seuls les cas de syndrome de Down à la naissance étaient significativement plus nombreux (le ratio de fréquence à la naissance rajusté selon l'âge de la mère était de 1,85, soit 1,19 à 2,76, selon une marge de fiabilité de 95 pour 100). Une corrélation négligeable a été établie entre les niveaux de rejet de tritium dans l'air et les cas de syndrome de Down à Pickering, mais aucune corrélation n'a pu être établie entre le syndrome de Down et les données obtenues à partir des postes de contrôle au sol. À Ajax, aucune anomalie n'avait de ratio de fréquence très élevé à la naissance, mais le risque de syndrome Down était élevé, mais de manière non significative statistiquement (le ratio du risque rajusté selon l'âge de la mère était de 1,46, soit de 0,80 à 2,44, selon une marge de fiabilité de 95 pour 100). Un lien sans signification statistique a été établi avec les niveaux les plus élevés enregistrés à partir des postes de contrôle au sol, mais aucun lien n'a été établi avec les nveaux de rejet de tritium.

5) **Conclusions :**

En résumé, l'analyse ne confirme pas l'hypothèse d'un taux accru de mortinatalité, de mortalité néo-natale ou de mortalité infantile aux environs de la centrale nucléaire Pickering. Depuis la mise en service de la centrale, en 1971, les taux de ces conditions n'ont pas été élevés en général. Ceci est vrai également des taux annuels observés dans les agglomérations situées près de la centrale. De plus, l'analyse ne confirme pas l'hypothèse d'une augmentation des cas de malformations congénitales à la naissance aux environs de la centrale dans 21 des 22 catégories diagnostiques de malformations congénitales établies pour l'analyse.

Les cas de syndrome de Down à la naissance étaient élevés autant à Pickering qu'à Ajax, mais il faut faire preuve de prudence dans l'interprétation de cette observation. Il n'y avait aucun lien cohérent entre les niveaux de rejet de tritium et les cas de syndrome de Down à la naissance; on ne peut exclure que le lien observé entre les cas de syndrome de Down et les rejets de tritium ou les concentrations mesurées au sol soit dû au hasard; le lien a été décelé dans une analyse comprenant de multiples tests de corrélation et certains liens significatifs pourraient facilement être attribuables au hasard. Le lieu de résidence de la mère au moment de la naissance reste à établir pour les mères atteintes du syndrome de Down à Pickering et à Ajax, et il n'existe aucune

donnée sur leur lieu de résidence au début de leur grossesse. En outre, le lien entre les cas de syndrome de Down et les faibles doses de rayonnement restera à déterminer après que les preuves existantes tirées des études épidémiologiques auront été regroupées. Enfin, l'exposition estimée des habitants de Pickering et d'Ajax, attribuable à l'existence de la centrale, est 100 fois inférieure à l'exposition due au rayonnement naturel de la région.

Il serait néanmoins prudent de poursuivre la recherche sur les cas de syndrome de Down à Pickering et à Ajax. Il faudrait d'abord examiner les archives des hôpitaux pour confirmer le lieu de résidence de la mère au moment de la naissance et le diagnostic du syndrome de Down, puis établir la durée de gestation des 38 cas de syndrome de Down. Si le lieu de résidence est confirmé et si l'on obtient la permission du ministère de la Santé de l'Ontario, du Hospital Medical Records Institute et des hôpitaux visés, les auteurs recommandent qu'une étude cas -témoins soit entreprise. Le groupe à étudier comprendrait les 38 enfants atteints du syndrome de Down qui sont nés entre 1973 et 1988 de mères qui habitaient à Pickering ou à Ajax au moment de la naissance. Un groupe de référence serait établi en choisissant d'autres bébés nés la même année à Pickering et à Ajax de mères du même âge. L'étude établirait le lieu de résidence de la mère durant et avant la grossesse, l'exposition possible à d'autres formes de rayonnement avant et durant la grossesse (par exemple, des rayons X) et des données sur d'autres facteurs confusionnels possibles, telles l'emploi de la mère et du père. Il faudrait aussi tenter d'obtenir les résultats des tests chromosomiques qui pourraient avoir été effectués pour certains cas de syndrome de Down. De nouvelles trisomies pourraient alors être séparées de celles qui ont été transmises (les translocations), fournissant ainsi une meilleure indication de la cause sous-jacente de ces cas.

L'étude a surtout traité de la santé publique plutôt que de questions étiologiques. Les auteurs ont voulu répondre à deux questions :

> *a*) Existent-ils des taux excessifs de malformations congénitales précises dans l'une ou l'autre des municipalités situées près de la centrale nucléaire Pickering, en général ou pour certaines années particulières?
>
> *b*) Existent-ils des liens entre les niveaux de rejet de tritium provenant de la centrale et les taux de certaines malformations congénitales?

Pour répondre à ces questions, il a fallu vérifier s'il existait un risque élevé pour divers effets affectant négativement la reproduction humaine durant plusieurs annéesdans plusieurs municipalités. Certaines associations statistiquement significatives sont presque inévitables dès que des corrélations multiples sont recherchées. Il faut donc que ce travail soit considéré simplement comme un exercice qui permet d'échafauder des hypothèses et ne pa ous-estimer la possibilité d'observer des liens apparemment significatifs, mais qui ne seraient dus qu'au hasard.

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TRITIUM RELEASES FROM THE PICKERING NUCLEAR GENERATING STATION AND BIRTH DEFECTS AND INFANT MORTALITY IN NEARBY COMMUNITIES 1971–1988

A. INTRODUCTION

In utero exposure to ionizing radiation at high doses (about 1 - 2 Sieverts) is known to increase the risk of birth defects in laboratory animals.[1] The level of dose and dose-rate to which the mother is exposed, as well as the stage of gestation when the radiation occurs, affects the magnitude of the risk. In spite of these observations in animals, the only significant birth defects observed in man have been an excess of microcephaly and mental retardation (or in less severe cases smaller head sizes and depressed mental performance) which were observed among children born to the Japanese mothers who received *in utero* exposure to ionizing radiation, estimated at two or three orders of magnitude higher than that of background radiation, released from the atomic bombs dropped on Hiroshima and Nagasaki.[2]

The literature contains few indications of a relationship between low level radiation and birth defects.[1,2,3,4,5] "The available studies of reproductive risk around properly functioning nuclear reactors have failed to disclose a persuasive genetic danger."[6] Studies of populations around nuclear plants based on vital statistics data have failed to demonstrate significant increases in the outcomes studied, which have included prematurity rates, birth defect incidence rates, birth defect mortality rates, and fetal and infant mortality rates.[7,8,9,10] A recent study of the Hanford Site in Washington State between 1968 and 1980 did find an increased birth prevalence of central nervous system defects but this could not be explained by the impact of plant emissions on the local population or by employment of the parents at Hanford.[11,12]

"*A priori*, one would expect these effects would be small, indeed beyond our abilities to detect an increased risk, for the estimated radiation exposure due to the presence of a properly functioning reactor is lower by a factor of 100 than the normal level of natural background radiation."[6] Doses and dose rates resulting from the measured releases of tritium from the Pickering Nuclear Generating Station (NGS) are derived by Ontario Hydro by modelling of the tritium dispersion patterns at the Pickering NGS. These calculations also support the contention that the radiation dose an individual in Pickering or Ajax would have received would be less by a factor of 100 than the average dose that members of the general public receive from naturally-occurring background radiation.[13]

A number of epidemiologic studies of low level radiation and Down Syndrome have been carried out, but the results have been contradictory. Reviews of those studies concur that the effect in humans of low-level prenatal irradiation on chromosomes remains indeterminate.[6,14,15]

Nevertheless, a recent report[16] by a freelance writer from Toronto has suggested a correlation between the peak releases of liquid tritium from the Pickering NGS and elevated mortality due to birth defects in a category of "other congenital anomalies" in the Township of Pickering

during the period from 1980 to 1985. An association between tritium release and neonatal infant death was also alleged. External review by the Ontario Ministry of Health suggested the study had serious data and analytic shortcomings. The Atomic Energy Control Board (AECB) decided it would be in the public interest to have a thorough and independent analysis of the birth defect and infant death data undertaken. Accordingly, the Board commissioned the Laboratory Centre for Disease Control, which runs the Canadian Congenital Anomalies Surveillance System, to examine more closely the risks of selected reproductive outcomes in the area and to examine whether the risk of any of these outcomes correlated with rates of tritium release from the power plant.

B. OBJECTIVES

The first study objective was to examine whether there were elevated rates of stillbirth, birth defects, or death in the first year of life, between 1971 and 1988, among offspring of residents of communities in close proximity to the Pickering NGS (within a 25 kilometre radius). The second study objective was to investigate whether there were any statistical associations between the monthly tritium emissions from the Pickering NGS and the rates of these reproductive outcomes.

It was not the objective of this study to estimate radiation exposure levels to which the women living in the vicinity of the plant might be exposed, nor to examine the plausibility or possible biological mechanisms by which *in utero* radiation exposure might occur.

The ecological design of this epidemiologic study imposes the same limitations on interpretation inherent to all studies of this design. The study deals with exposure at the level of communities as opposed to the individual. Accordingly, the study can only identify associations at the level of community--associations which may not hold for individuals. Furthermore, association is only one tenet of the detailed evidence required to make a causal judgement.[17]

C. METHODS

1. DATA SOURCES

a) Tritium Releases:

Data on monthly releases of airborne and waterborne tritium from the Pickering NGS for the period 1971-1988 were obtained from the AECB. The data had been supplied to AECB by Ontario Hydro's effluent monitoring program.[18] Data on other radioactive releases from the plant were also obtained from the AECB so that potential confounding of any tritium-

reproductive outcome relationship could be evaluated. Composite monthly tritium airborne concentration data collected from Health and Welfare[19] and Ontario Hydro[13] environmental ground monitoring stations located near the plant were made available after a preliminary analysis of release data had been reported.

b) Birth Defects:

Case Definition: The International Classification of Diseases-9 (ICD-9) rubrics[20] were used to define cases. Codes falling within the Congenital Anomalies chapter (ICD-9 codes 740.0-759.9) were included with the exception of undescended testes, skin tags, birth marks and patent ductus arteriosus. (See Appendix A for details.)

Data on birth defects were obtained from the Canadian Congenital Anomalies Surveillance System (CCASS) operated by Health and Welfare Canada. Prior to 1973 Ontario did not participate in CCASS and a registry of birth defect data did not exist. For the period 1973-1977 the Ontario Department of Health provided CCASS with data on birth defects reported in the first year of life and ascertained through Physicians Notices of Birth, Physicians Notices of Stillbirth, death certificates, and admission-discharge summaries sent by hospitals when a defect was noted.

For the period 1978 to 1988 the CCASS database for Ontario was compiled exclusively from a computer search of anonymized individual hospital admission-discharge summaries compiled by the Hospital Medical Records Institute (HMRI). The HMRI database includes a record for every separation from a public hospital in Ontario for the period 1978-1988. All stillbirths and every separation record including a diagnostic code for a birth defect for a child under one year of age at the time of discharge were chosen for the birth defect registry. Multiple admissions relating to the same child were consolidated. Appendix B describes CCASS in more detail and the rationale underlying the move to an HMRI-based system.

c) Live Births, Stillbirths and Infant Deaths:

Data on all live births, stillbirths and infant deaths among Ontario residents between 1971 and 1988 were obtained from Statistics Canada. The data were recorded and accumulated by Ontario's Registrar of Vital Statistics and copies of registration documents are made available to Statistics Canada for compilation of aggregate national statistics. Live birth counts were also retrieved from the HMRI database for the analysis of birth defects so that ascertainment and coding of birth defects numerators and denominators would be consistent.

2. ANALYSIS STRATEGY

a) Study Area

The study area was designated as the area within a radius of approximately 25 kilometres of the Pickering NGS. This radius has an approximate correspondence to the geographic boundaries used for coding the place of residence in the datasets available. For analysis, the area was split into its six census subdivisions, as defined by the Canada's Standard Geographic Code Classification[21].

Appendix C contains a map showing the 25 kilometre radius and the six census subdivisions it contains: the Townships of Pickering, Ajax, Markham, and Whitby, the City of Oshawa and the Borough of Scarborough. A copy of a topographical map displays the built up areas within close proximity of the plant. Appendix D lists the Standard Geographic Classifications and the Ontario Ministry of Health codes[22] for the areas and the changes in the codes during the study period. Although the Ontario Ministry of Health uses different codes than the Federal Government, there is a one-to-one correspondence at the municipality level for the defined areas. Also included in Appendix D is a map of the boundary changes that occurred in 1974.

b) General Strategy

Figure 1 depicts the main study elements. The area was divided into the census subdivision areas so that localized effects would not be missed because of dilution within a larger area. Analysis on the basis of areas smaller than the census subdivision were impractical because of the exceedingly small expected number of cases of any of the study outcomes. Furthermore, postal code must be used to identify residences below the census subdivision level but postal code was not routinely coded in the HMRI database before 1985, the 1973-1977 birth defect registry, the live birth or the infant death files.

One general hypothesis underlying the study was that if any reproductive problems related to releases from the reactors were present, the highest risks would occur in Pickering and/or Ajax because of their physical proximity to the plant and because their drinking water supplies during the 1970's were taken from Lake Ontario at locations far closer to the plant than the other townships. (Appendix E). If an effect was not seen in either of these two communities, it would be difficult to envision an effect in the other communities. A second hypothesis was that if the risk of a specific reproductive outcome over the study period was neither elevated in Pickering or Ajax in comparison to Ontario nor elevated in comparison to nearby municipalities, it was generally not an appropriate outcome to examine for associations with tritium. However, for the general examination of birth defect rates in Phase 2 analysis we did correlate each defect group with each tritium measure.

A wide range of reproductive outcomes was examined because we wanted to provide a general picture of the reproductive health in the Pickering vicinity. The initial categorization of birth

defects into three groups was chosen to keep them similar to those in McArthur's report, so that the concerns he raised could be directly addressed. Mental retardation was not examined because we are unaware of any data source for Ontario or the vicinity of Pickering where relevant information has been collected in a standardized form on a population basis. Spontaneous abortion (miscarriage), the most common adverse reproductive outcome, was not examined because of considerable methodological problems associated with ascertainment.[15] (See the discussion section for further explanation.)

We chose to do a systematic screening of many outcomes by municipality and by year to elucidate any potential reproductive health problems in the area. However, the interpretation of the results of such an exercise requires caution because statistically significant results can occur by chance when many statistical tests are performed.

3. DATA ANALYSIS

3.1 Estimation of Relative Risk

In this study standardized mortality ratios[23] (SMRs) are used to evaluate risk of death and standardized birth prevalence ratios (SIRs) are used to evaluate risk of birth defects. The infant mortality ratio is the ratio of the observed number of deaths to the number of deaths that would be expected to occur in an area with as many live births tabulated by year of birth. The expected number of deaths is calculated by multiplying the area live birth count in a year by the provincial infant death rate.

The term birth prevalence is used to distinguish it from incidence which would include defects in all conceptuses, many of which may spontaneously abort. For the birth prevalence ratio the observed is the number of birth defect cases ascertained in stillbirths or during the first year of life. The expected number of cases is calculated by multiplying the yearly area live birth plus stillbirth count by the provincial birth defect birth prevalence rate.

It is well established that older maternal ages are associated with much higher risk of having a Down Syndrome child.[24] Therefore, for Down Syndrome birth prevalences the expected numbers of cases were also adjusted for the maternal age distributions in each county, which were established from vital statistics data.[25,26] For Pickering and Ajax the maternal age distributions were obtained by extracting all HMRI delivery records for each of these municipalities. The Down Syndrome rates were indirectly standardized because the maternal ages of the Down Syndrome mothers were not in our birth defect database and it would have been difficult to obtain them for all Down Syndrome cases in the province.

To facilitate interpretation, approximate 95% confidence intervals (CIs) were obtained as an estimate of the uncertainty in the ratios, using Byar's method.[27] A conventional level of alpha=0.05 was chosen for the confidence intervals to conform with standard practice.

Based on biostatistical theory, the actual underlying incidence ratio will fall within the 95% confidence interval 19 times out of 20. A 95% confidence band that does not include 1.0 should occur by chance, on average, only once in 20 tests, if the actual rate in an area does not differ from that of the comparison population. For SIRs based on small populations the confidence intervals are wide. As the observed population becomes larger, the SIRs become more stable and this is reflected in a narrower confidence interval.

3.2 Use of Tritium Release and Ground Monitoring Data

The monthly airborne and waterborne tritium release levels from the Pickering NGS between 1971 and 1988 are plotted in Figures 2 and 3. For this analysis, the 4-month high value was calculated as the highest monthly emission level over a four month period starting with the index month. The 4-month average monthly emission level variable was calculated as the average of the four monthly values in the four month period starting with the index month. The 4-month high and the 4-month average value were calculated for every month for waterborne and for airborne tritium releases from the reactor.

These 4-month high and average tritium emission (release) levels were categorized into quartiles with the lowest 25% of release values assigned category 1. The release levels were quite skewed, with a wide range of release values in the highest release quartile. Therefore the fourth quartile was split to create a fifth category with the highest 12.5% of monthly releases. The four resulting release variables are described in Appendix F and marked to the right of the plots in Figures 2 and 3.

Births, CNS defects, congenital heart defects, and the balance of defects were then categorized by month and year of birth in each study municipality. Emission categories were assigned to each month and year of birth after moving them forward 9 months. Births of normal gestation (36-40 weeks from fertilization) would on average be assigned a tritium level for a time window which would on average include a period 2 weeks before fertilization and the entire first trimester of pregnancy. Figure 4 illustrates this lagging procedure and the time period that would be covered for births of various gestations and occurring at different times in the month. Birth defect rates were then calculated for each emission level and relative risks computed comparing rates within each of the other emission categories to the lowest emission category.

Locations of Health and Welfare and Ontario Hydro ground monitoring stations are presented in Appendix C. The Health and Welfare ground monitoring data were categorized into five levels using the same method of categorization as the release data. Health and Welfare monitoring data were chosen over the Ontario Hydro monitoring data because the data were more complete (fewer missing values), easier to extract (not in log graphs) and some of the sampling points were located closer to the communities of interest. As well, sampling points from the two programs in close proximity of each other registered similar fluctuations; agreement was particularly good between the nearby samplers for months with higher levels.

Health and Welfare ground monitoring data from sampling locations 1, 2 and 3 were averaged to form an index for Pickering exposure. Stations 4 and 5 were averaged for an Ajax index. Where a monthly value from a monitoring station was missing, the station was left out of the average calculation. The monitored monthly levels for each station and a table of summary four month variables are described in Appendix F. Correlations between the five ground monitoring station levels, and with the airborne release levels are also presented in Appendix F. The wind rose histogram for the Pickering NGS for 1988, describing the directions and strengths of the winds that blew over the course of the year, is also presented in the Appendix and helps to explain the generally low correlations between the different monitors.

3.3 Data Analysis

Data analysis proceeded in four phases:

a) Phase One - Systematic General Screening

The first phase involved a systematic screening in each of the six municipalities of the following reproductive outcomes: stillbirths, perinatal deaths, neonatal deaths, all infant deaths, neonatal birth defect deaths, infant birth defect deaths, congenital heart defects (CHD), central nervous system (CNS) defects and all birth defects except CHD and CNS defects. (See Appendix A for definitions.) Outcomes were examined year by year and summarized over the entire study period. The underlying cause of death among infants, as coded on the death certificate, was also examined.

b) Phase Two - Tritium - Birth Defect Group Associations

In the second phase of the study the monthly levels of tritium emission (release) from the Pickering NGS and the monthly airborne concentrations of tritium in air water vapour sampled at Health and Welfare ground monitoring stations were each correlated with the total birth defect cases, CNS defect cases, CHD cases, and cases with defects except CNS and CHD, in each of the six study municipalities.

A traditional 2 x K stratified analysis[23] was performed using the EGRET microcomputer statistical package[28]. The analysis was stratified into the two time periods 1973-1977 and 1978-1988 to account for the somewhat different birth defect ascertainment protocols used and the substantial differences in many birth defect rates in the two time periods (see Appendix G). The Mantel-Haenszel procedure was used to summarise risk over strata. The lowest release quartile was used as the referent release or ground monitoring category.

c) Phase Three - Specific Defect Analysis

To examine whether more specific defects, rather than the broader groupings, might be occurring at elevated rates, 22 more specific birth defect categories (see Appendix A) were screened for Pickering and Ajax for high SIRs in particular years or over the entire 1973-1988 time period. Individual defects were chosen for study because they had received attention in the radiation literature or they had high population birth prevalence. The balance of defects were grouped into anatomical categories for evaluation to limit the multiple testing problem, to avoid highly unstable rates that occur with rare defects in small populations, and to allow some reasonable chance of observing statistically significant results without very high relative risks.

Specific defects or anatomical categories which had a 1973-1988 birth prevalence ratio which exceeded 1.5 and which were statistically significant at the 95% confidence level were then examined with the stratified Phase Two analysis. This limitation was imposed to limit the number of false positive results which might occur if relative risks were calculated for all defects for all tritium variables.

d) Phase Four - Mapping

Finally, maps of Ontario were produced with categorized birth prevalence ratios for specific defects. These were produced to put the local Pickering results into a provincial context. Ratios for entire counties were plotted where no large municipalities existed. Ratios for individual municipalities and for the county residual were plotted for municipalities with at least 6,000 births between 1973 and 1988, so that communities similar in size to Ajax and all larger municipalities would be plotted. Municipalities within Toronto and Ottawa were collapsed because it is known that large misclassification of residence to the city rather than the municipality can occur.

The maps were colour-coded with risk corresponding to the place on the colour spectrum as indicated in the map legends. Red through brown indicated elevated risk, green and aqua indicated risk near unity, and blue and purple substantially lower risk than the province as a whole. The rates were plotted from 1974-88, not 1973-1988 because of a number of substantial boundary changes made at the beginning of 1974.

D. RESULTS

a) Phase One - Systematic General Screening

Stillbirths and perinatal, neonatal and infant mortality SMRs are presented in Table 1.1 for the six study municipalities. SMRs were consistently below one in all communities except Oshawa where risk was about the same as the provincial average. Stillbirths were elevated in Oshawa but perinatal mortality, which combines stillbirths and first week-of-life deaths, was not elevated.

Table 1.2 presents SMRs for infant deaths by underlying cause of death as coded on the death certificate. No cause of death was significantly elevated in any municipality. (The elevated circulatory death risk was based on one case in the entire 18 year period.) Risks of death attributed to congenital anomalies (birth defects) were all similar to those for all of Ontario. In Pickering each SMR was significantly lower than for the province.

Tables 2.1 and 2.2 present birth prevalence and mortality ratios for infants with CNS, CHD and the balance of birth defects. In Appendix H infant mortality and birth defects are plotted by year for each study municipality.

There was no indication of a pattern of excess risk for any of the outcomes in any of the study municipalities. The one exception was congenital heart defects in Oshawa with an overall SIR of 1.41 (CI 1.26 - 1.57) and six different years where the SIR was between 1.5 and 2.0 and the 95% CI did not include 1.0. Stillbirth rates were high in Oshawa in the early 1970's but when combined with neonatal deaths the SIRs were not statistically significant. (The assignment of deaths occurring near the time of birth can vary between these two categories.)

b) Phase Two - Radiation-Birth Defect Group Associations

Table 3.1 summarizes the phase two tritium release-birth defect relative risk analysis for Pickering and Ajax. The analysis related to release data in the other four municipalities produced no increased relative risks associated with the higher categories of airborne or waterborne tritium release. For Pickering and Ajax no consistent patterns of increased relative risks with higher waterborne tritium releases were found.

However, the highest levels of airborne tritium releases (still less than one percent of the derived emission limits) were associated with an elevated birth prevalence of CNS defects in Pickering. The correlation was restricted only to the highest emission category--there was no correlation or trend among the four lower emission categories. Table 4 presents the odds ratios and 95% CIs by release level, stratified by reporting period. Five children with a variety of CNS defects (1 anencephaly, 1 microcephaly, 1 spina bifida with hydrocephalus, and 2 children with the unspecified CNS defect code reported) were born between January and July 1978 in Pickering following the period of relatively high airborne tritium release between April and October 1977. They account for the high birth prevalence corresponding to the highest release category.

Table 3.2 presents an analysis similar to that in Table 3.1, using Health and Welfare ground monitoring data. The association between CNS defects in Pickering and the highest release levels could not be replicated with ground monitoring data. In fact, no associations between the levels of tritium picked up at the ground monitoring stations and CNS, CHD or the balance of defects were apparent.

c) Phase Three - Specific Defect Analysis

Tables 5.1 and 5.2 present Pickering and Ajax birth prevalence ratios for the specific birth defects and categories outlined in Appendix A. All counts are case-based--a child with two anomalies in the same category would be counted once. For Ajax, none of the birth defects or categories had significantly elevated risks.

In Pickering, Down Syndrome was the only defect with significantly elevated birth prevalence (maternal age-adjusted birth prevalence ratio 1.85, 95%CI 1.19-2.76). A correlation, not statistically significant, was found between airborne tritium release levels and the Pickering Down Syndrome cases (Table 6) but no correlation was found between Down Syndrome and the ground monitoring data. In Ajax, where the Down Syndrome birth prevalence was also elevated (although not statistically significantly so) (maternal age adjusted birth prevalence ratio 1.46, 95% CI 0.80-2.44), an association which was not statistically significant was found with the highest ground monitored tritium levels but no correlation was found between Down Syndrome and the airborne tritium release levels (Table 7).

Appendix I includes a tabular summary of the maternal age-adjusted birth prevalence ratios for Down syndrome by year for each of the six municipalities.

Advanced maternal age is an important risk factor for Down Syndrome. The risk associated with different maternal ages, the distribution of mothers' ages in Pickering and Ajax and the expected numbers of Down Syndrome cases in Pickering and Ajax are presented in Table 8. Maternal ages are not available from the birth defect file so admission-discharge summaries for deliveries (i.e. the mothers' records) were extracted from the main HMRI database for Pickering and Ajax births between 1978-1988.

In the HMRI database, we were able to match mothers' hospitalizations at time of delivery with the Down Syndrome children. Unfortunately, we were only able to locate 24 of the 32 mothers' delivery records for Pickering and Ajax Down Syndrome cases between 1978 and 1988. The distribution of maternal ages for the located mothers was not different than that which would be expected based on age-associated risk and the population age distributions (see Table 8). There are a number of possible explanations why we were unable to locate all the delivery records. The problem should be resolved through a follow up of individual hospital records for defect and residence confirmation.

Postal codes first appear in the HMRI file in 1984 for 35% of records, in 1985 for 85% of records, and after 1985 in over 95% of records. For 19 of the 20 Down Syndrome cases born after 1983 in Pickering and Ajax a postal code had been recorded. For the 16 of 19 cases where a proper Ajax or Pickering code was recorded, we marked on a city street map the street that included the case's postal code (generally one to three suburban street block faces). On simple visual inspection, there did not appear to be a clustering of the mapped cases or a tendency for the residences to be closer to the nuclear plant. No formal spatial analysis was performed. We do not present that map because of confidentiality concerns for the individual cases involved.

d) Phase Four - Mapping

Finally, to examine the variation in birth prevalence for Down Syndrome across Ontario, we plotted Down Syndrome birth prevalence ratios for 1974-1988 adjusted for maternal age distribution and year of birth for the approximately 100 geographic areas in Ontario where a similar number or more births than in Pickering or Ajax occur each year (see Map 1). A second county besides Pickering had a birth prevalence ratio greater than 1.5 and statistically significant at the .05 level. Several geographic areas had a Down Syndrome birth prevalence ratio similar to Ajax--between 1.25 and 1.49 but not statistically significant.

To see how unlikely an elevated risk profile in Ontario like the one for Down Syndrome was, maps were produced for spina bifida, respiratory anomalies, and cleft lip and palate, three other anomalies with birth prevalence similar to that for Down Syndrome (see Maps 2, 3, and 4). The maps were quite consistent in the sense that each map displayed one or two areas with risk over 1.5 and significant at the .05 level, and several areas with a risk between 1.25 and 1.49 but not significant. These other maps suggest that the Down Syndrome birth prevalence profile for Ontario is not unlike that for other birth defects of similar birth prevalence. However, it is noteworthy that elevated birth prevalence for Down Syndrome occurred in the two municipalities adjacent to the nuclear plant.

E. DISCUSSION

1. CNS Risk

The association between CNS defects in Pickering and the highest airborne tritium releases seems likely to be a chance occurrence. First, the association of CNS defects with tritium airborne emissions was isolated only to the highest emission level. No correlations or trends were seen among the four lower emission levels. Second, the association could not be reproduced when the Health and Welfare ground monitoring data for the three samplers in the direction of Pickering were substituted for the airborne tritium release data. This is not too surprising given the low correlation between the airborne tritium release levels and the ground monitored levels, presumably the result of fluctuations in wind speed and direction in Pickering over the course of the year (as documented by the wind rose histogram in Appendix F).

Third, neither microcephaly (known to be related to ionising radiation exposure in the Atomic bomb studies[2]) nor any other specific CNS defect was particularly high during the entire period or during 1974 or 1978 when the highest rates were recorded. There was never more than one microcephaly case in Pickering or Ajax in any one year. Fourth, the overall risk of CNS defects for 1973-1988 was 20 percent lower for Pickering than for Ontario as a whole. Fifth, no increased overall risk of CNS defects, nor any association between tritium releases or monitored levels could be documented in Ajax, which is more consistently downwind of the reactor site.

2. Down Syndrome Risk

In Pickering, Down Syndrome birth prevalence for the period 1973-1988 was significantly elevated (age-adjusted birth prevalence ratio 1.85, 95%CI 1.19-2.76). A correlation that was not statistically significant using 95% confidence limits was found between airborne tritium release levels and the Pickering Down Syndrome cases, but no correlation was found between Down Syndrome and the ground monitoring data. In Ajax, where the Down Syndrome birth prevalence ratio was also elevated for the period 1973-1988 (although not statistically significantly so) (age adjusted birth prevalence ratio 1.46, 95% CI 0.80-2.44), an association that was not statistically significant using 95% confidence limits was found with the highest ground monitored levels.

Maternal age is the major known risk factor for Down Syndrome.[15] The maternal age distribution for Ajax was quite similar to Ontario as a whole (see Appendix I) with about 29% of births to women 30 or over between 1978 and 1988. Pickering mothers were slightly older on average than their Ajax and Ontario counterparts, with about 36% of mothers 30 or over for births between 1978 and 1988, the excess primarily occurring in the 30-34 year age range. Accordingly, the addition of maternal age adjustment did not change the risk ratios substantially. The unadjusted risk ratio for Pickering was 1.94 (95% CI 1.24 - 2.88) and for Ajax 1.39 (95% CI .76 - 2.33).

The maternal age adjustment procedure appears to appropriately adjust the expected number of cases. The procedure quite accurately predicted the expected numbers of cases of Down Syndrome in Ontario (See Appendix I). For the Down Syndrome cases in Pickering and Ajax where the mother's age could be established, the age distribution was as one would expect. The elevated birth prevalence could not be attributed to an excess among women 35 and over.

When the existing evidence from the dozen epidemiologic studies of Down Syndrome and low level radiation is examined, the effect of prenatal irradiation on chromosomes remains indeterminate. Kline and colleagues describe some of the difficulties involved in coming to a conclusion about the evidence:

> "Taking the whole array of studies of irradiation and trisomy together, those associations that appear are not consistent, and the inconsistencies seem not to be explained by such known variable factors as dose. Comparison across studies is complicated not only by differences in design but by problems in ascertaining and specifying exposure. Several of the case-control studies are liable to recall bias: parental reports of exposure could differ between cases with abnormal offspring and controls with normal ones. The level of exposure can often be no more refined than the dichotomy that exposure, say to x-irradiation in some diagnostic procedure, did or did not occur; unknown variations in dose may then contribute to inconsistencies. Untoward radiation doses - as in atomic bombings and nuclear accidents - have often been imprecisely estimated."[15]

Interpretation of this elevated birth prevalence must also be very cautious for reasons including the following: there was no consistent pattern between tritium releases or monitored levels in

Pickering and Ajax and Down Syndrome rates--chance could not be ruled out for the associations seen, i.e., they were not statistically significant; the level of tritium exposure in Pickering and Ajax is very low (a very small fraction of the natural background radiation level); the multiple testing problem cannot be overlooked; maternal residences at birth for Down Syndrome mothers in Pickering and Ajax have not been verified through hospital records; and the literature is inconsistent as to the relationship between irradiation and Down Syndrome in human beings.

3. The Power to Detect Significant Increases in Risk

In studies of birth defects, there is often a tension between grouping defects that occur rarely to increase the number of events observed, and keeping the individual defects separate because there may be differences among their underlying etiology. In this study we presented individual defects of special interest because of high birth prevalence or because of the radiation literature (e.g. Down Syndrome and specific CNS defects). We also "covered the waterfront" with anatomical system-based grouping of other less common defects because of a desire to provide a general scan of reproductive health in the vicinity of the nuclear plant. Less common defects were generally grouped to limit the multiple testing problem, to avoid highly unstable rates, and to increase the chance of seeing a statistically significant increase in birth prevalence without requiring the high risk ratios needed for rare events in small populations.

Power calculations[23] are used to determine the ability of a study to detect excesses of risk of a certain magnitude. As the power is contingent on factors including the background risk and expected number of cases, it will vary greatly depending on the type of birth defect or other reproductive outcome, the size of the community, and the length of the time period of interest. Therefore we do not see it as particularly useful exercise here. Confidence interval widths associated with the presented risks give a good indication of our ability to evaluate individual risks. For example, consider an anomaly of low birth prevalence like microcephalus for the entire study period in Pickering. In spite of the fact that the risk ratio was less than one, we cannot rule out with 95% certainty the possibility that the actual underlying risk in the community might be as low as .35 or high as 2.08. Nevertheless the most probable risk ratio is the calculated point estimate of .96.

4. Spontaneous Abortion

Spontaneous abortion is the most common adverse reproductive outcome.[15] It is a potentially important screening device[29] because the birth prevalence of a defect only reflects the occurrence of a defect among those fetuses that survived until birth. It was not examined closely in this report because of substantial methodological problems associated with ascertainment[15] from the available data sources. A small percentage of spontaneous abortions are reported in hospital. Rates have been reported for Pickering and for Ajax between 1976 and 1986[30] and were much lower than the overall Ontario rates in almost every year (see graph in Appendix J).

However, we chose not to examine this outcome more closely because of the high potential for misleading results. With an outcome where the ascertainment is a small percentage of the actual incidence, a number of extraneous factors which affect ascertainment as opposed to incidence (e.g. hospital bed availability) could substantially alter the rates of spontaneous abortion picked up through hospital inpatient data. The Ajax and Pickering data in Appendix J are a case in point. There is no reason to expect *a priori* that Pickering and Ajax would have a true incidence of spontaneous abortion consistently 25 to 60 percent lower in the 1980's than Ontario.

5. Potential Biases

5.0 Ecological Design

When an association is seen in an ecological study (where the measures of exposure are at the community rather than individual level), bias in the form of the ecological fallacy can easily occur.[31] The community average estimate of potential exposure will not necessarily represent the exposure profile of the individuals with the outcome of interest.

5.1 Birth Defects Data Quality

In any study of birth defects, differences in case ascertainment can be an important source of bias.[32,33] The substantially higher rates of birth defects reported between 1978 and 1988 than between 1973 and 1977 in CCASS demonstrate an important increase in ascertainment. As ascertainment improves, the potential for bias in reporting is likely to decrease. Accordingly, we have less confidence in the 1973-1977 rates than the 1978-1988 ones. If one hospital was particularly conscientious about sending reports on defects in the 1973-1977 period, there is no reason to think that the rates would be lower than the 1978-1988 ones, but they would be considerably higher than from other hospitals during the older time period. However, the elevated risks for Down Syndrome were similar in both time periods and elevated for Ajax only after 1977.

We feel reasonably confident that the 1978-1988 database achieves a high ascertainment of serious birth defects among live born children because: 1) the overall rates of defects in general and of specific defects are in line with the rates of other quality monitoring systems around the world,[34] with an all (non-trivial) birth defect case rate between four and five percent of live births and stillbirths; 2) the rates are in line with other provincial monitoring systems, notably Manitoba and British Columbia; 3) the diagnoses are coded by trained medical records technicians in each hospital; 4) HMRI performs its own data quality checks (the release is pending of a validation study where some 3000 charts from 40-odd hospitals were recoded and compared with the original coding) and 5) the scanning of all hospitalizations during the first year of life should minimize the problem of diagnoses missed at birth for the vast majority of more serious defects, i.e., those that require subsequent hospitalization. The ascertainment of birth defects among stillborn children is generally poor and this is likely the case in the HMRI database.

5.2 Place of Residence

There are several issues to address concerning the quality of residence coding. First, there were significant boundary changes in 1974 with the creation of the Regional Municipality of Durham. In 1974 part of Pickering was incorporated into Scarborough and part into Ajax, resulting in a drop in the recorded number of live births in Pickering between 1973 and 1974 from 513 to 384. Coding errors following boundary changes could have occurred to spuriously elevate or lower outcome rates.

The 10-15% shortfall in live births between 1978 and 1988 in Pickering as ascertained through the HMRI database in comparison to the Statistics Canada database created from documents from Ontario's Registrar General's Office is of concern (Appendix K). However, by using the HMRI database for live birth ascertainment for calculating birth defect rates, it is unlikely that a bias will be introduced. Only if children with birth defects were more likely (or more unlikely) to have residences correctly coded would the rates be biased. There is no easy way to properly evaluate this bias, but no reason to expect it either. The residence coding is generally done at the time of admission, based on the stated address, which in the majority of birth defect reports is before the birth and any knowledge of the outcome. Of the 32 Down Syndrome cases born between 1978 and 1988 in Pickering and Ajax (before 1978 diagnosis date is not on the dataset), 27 were diagnosed at birth.

The failure to locate all of the delivery records for the mothers of Down Syndrome children in Ajax and Pickering is somewhat troubling. It is not possible to select records based on scrambled health care number, which would allow us to directly search for mothers' delivery records of the Down Syndrome cases. Actually extracting (as opposed to counting) large numbers of records (e.g. all delivery records for Ontario) is a monumental task. All delivery records for Pickering and Ajax were extracted but if residence was miscoded, a delivery code was entered wrong or the insurance number was different or missing, then we have no way to link delivery and newborn.

We initiated a pilot study through HMRI to see if we could get hospitals to pull charts to confirm diagnostic and residence coding. We chose to examine only the CNS defect cases and Down Syndrome cases in Pickering in 1978 because this was a pilot--apparently the first time HMRI had actually requested hospitals to pull charts for an epidemiologic research study. Hospital and individual confidentiality were maintained because we simply passed HMRI the scrambled hospital number, the scrambled health care number and the admission date. We received copies of admission separations with identifiers removed and the scrambled numbers written in.

It was reassuring that there was good agreement on diagnostic and residence coding for the Pickering birth defects cases for 1978 that were checked through hospitalizations. As well, among the 19 Pickering and Ajax Down Syndrome cases where a postal code was reported, 16 cases had a legitimate Pickering or Ajax code. Furthermore, among the Down Syndrome cases where multiple admissions were found (27 of the 38 cases) there were very few coding inconsistencies.

5.3 Potential Confounders

Limited information is available on the geographic distribution (particularly at the municipal or county level) of factors which might potentially alter the adverse reproductive risks in a particular community. This study has not considered how potential confounding factors including birth order, ethnicity, socioeconomic status, alcohol consumption, smoking prevalence and x-rays during pregnancy might affect a woman's risk of an adverse outcome. Nevertheless, we feel it is unlikely that any of these would substantively change the results because we have no reason to suspect that the populations in Pickering and Ajax vary substantially on these factors from Ontario as a whole.

We did not examine non-tritium radioactive releases from the Pickering NGS in a detailed way. However, our general examination of the other release patterns did not suggest that they were confounding the associations we observed.

5.4 The Choice of Tritium Measures and Gestational Age Assumptions

We chose two measures of tritium levels for both release data and ground monitoring data to correlate with pregnancy outcome, a 4-month high value and a 4-month average. The ground monitoring data were averaged for stations in the directions of the community of interest. More sophisticated measures could have been developed, taking into consideration such factors as the distance of the stations from the plant and the distribution of the residences in relation to the monitoring stations. We chose two measures we felt were simple to understand, described the most important features of the tritium level during the first trimester, and would be unlikely to miss an effect if one was present. We felt they were of appropriate sophistication given the fact that we had no information on gestational age among our birth defect or infant death cases and all the tritium data was given to us as monthly figures. With the almost four week variation in "normal" pregnancy gestation, more specific measures seemed inappropriate for this initial analysis.

We assumed the pregnancy outcomes were of normal gestation in the absence of a systematic way to classify them otherwise. However, this imprecision in the tritium level variables, the assumed gestation, and the fact that there is generally a short critical period during organogenesis when teratogenesis is most likely to occur could result in a diluted estimate of risk if a real effect was present, or produce a spurious association. To take a closer look where a relationship was noted, it would be necessary to obtain gestational ages for the cases and develop more sophisticated tritium measures.

6. Recommendations for Future Study

We recommend that further investigation be initiated, first to complete the confirmation of maternal residence at birth and defect diagnosis and to establish gestation through hospital charts. If the residences are confirmed and permission can be obtained from the Ontario Ministry of

Health and HMRI, it would seem prudent to undertake a case-referent study.[23] In a case-referent study, the experience of the case group is compared to that of a referent group to examine similarities and differences in factors in the two groups' experiences which might explain the differences in outcome. The case group would consist of the 38 Down Syndrome children born between 1973 and 1988 to mothers resident in Pickering or Ajax at the time of birth. A referent (comparison) group would be compiled by selecting births from Pickering and Ajax matched on birth date and born of mothers with similar maternal ages.

The study would establish pregnancy gestation, maternal residence during and before pregnancy, and compare potential exposure to radiation before and during pregnancy (e.g. x-rays)[34] and other information such as mother's and father's occupation. If either parent had worked at the nuclear plant, their monitored radiation exposure history would be established. An attempt should be made to obtain results of chromosomal tests that may have been done for some of the Down's cases. Newly arisen trisomies might then be separated from those that were transmitted (the translocations), providing a better indication of the etiology underlying the cases.

F. CONCLUSIONS

Overall, this analysis does not support a hypothesis of increased rates of stillbirths, neonatal mortality or infant mortality in the vicinity of the Pickering NGS. Since the plant's start up in 1971, the rates of these conditions were neither high overall, nor were the patterns of yearly distribution unexpected in any years among any of the communities in the vicinity of the plant. This report's findings and further analysis of McArthur's data (see Appendix L) do not support the claim by the McArthur report that there is elevated infant mortality in Pickering due to releases of liquid tritium from Pickering NGS. Furthermore, the analysis does not support a hypothesis of increased rates of birth defects in 21 of the 22 diagnostic categories studied.

Down Syndrome birth prevalences in Pickering and Ajax were elevated. However, interpretation of the elevated Down Syndrome birth prevalence requires caution for reasons including the following:

1) There was no consistent pattern between tritium releases or ground monitoring data and the Down Syndrome birth prevalence.

2) Maternal residence at birth for Down Syndrome mothers in Pickering and Ajax needs to be verified. As well, we have no information about the mothers' places of residence before or during pregnancy.

3) The associations are based on small numbers. Even a small number of coding errors (residence or defect codes in particular) could have produced a spuriously significant observation.

4) Present understanding of tritium and its dispersion in the environment would suggest that the amounts of tritium released from the Pickering reactor would not result in any important exposure of the mother or fetus. Background radiation would be likely to contribute 100 or more times the radiation dose as the tritium emissions from the nuclear plant.

5) The association between Down Syndrome and low level radiation remains indeterminate when the existing evidence from epidemiologic studies is summed.

Nevertheless, we feel that more detailed examination of the elevated rates of Down Syndrome would be prudent. Mother's residence at the time of birth of the Down Syndrome cases should be confirmed. If permission can be obtained from the Ontario Ministry of Health and HMRI, we feel it would be useful to initiate a case-referent study using the 38 Down Syndrome children born between 1973 and 1988 to mothers resident in Pickering or Ajax.

The study has primarily addressed public health as opposed to etiologic issues. We have tried to answer two questions:

a) Are there excess rates of specific reproductive outcomes in any of the municipalities in the vicinity of the Pickering NGS, overall or in specific years? and

b) Are there any associations between radioactive releases from the plant and specific reproductive outcomes?

The attempt to answer these questions has required screening a variety of adverse reproductive outcomes for elevated risk over a series of years, in a number of municipalities. Some statistically significant associations are a likely outcome when many statistical tests are done. Therefore, such a screening must be viewed as a hypothesis-generating exercise and the potential for significant associations by chance alone should not be underestimated.

Table 1.1 Stillbirth and Infant Mortality Ratios for Pickering Area, 1971–1988 (Reference Ontario)

	Scarborough		Markham		Pickering		Ajax		Whitby		Oshawa	
Death Category	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag
Stillbirth	1.16		0.84	*	0.71	**	0.97		1.04		1.23	*
Perinatal Mortality	0.85	**	0.90		0.69	*	0.73		0.47	**	1.03	
Neonatal Mortality	0.85	**	0.86		0.75	*	0.73	*	0.59	**	1.02	
Infant Mortality	0.85	**	0.80	**	0.70	**	0.80		0.66	**	0.96	

S.M.R. Standardized Mortality Ratio

Flag ** S.M.R. is significantly different from Ontario overall, P-Value < 0.01
Flag * S.M.R. is significantly different from Ontario overall, P-Value < 0.05

Table 1.2 Infant Mortality Ratios for Pickering Area by Underlying Cause of Death, 1971–1988 (Reference Ontario)

	Scarborough		Markham		Pickering		Ajax		Whitby		Oshawa	
Cause of Death	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag	S.M.R.	Flag
Circulatory Disease	0.44		0.72		0.00		1.86		0.00		0.49	
Respiratory Disease	0.40	**	0.22	*	0.76		0.84		1.20		0.74	
Congenital Anomalies	0.93		0.95		0.97		1.04		1.00		1.01	

S.M.R. Standardized Mortality Ratio

Flag ** S.M.R. is significantly different from Ontario overall, P-Value < 0.01
Flag * S.M.R. is significantly different from Ontario overall, P-Value < 0.05

TABLE 2.1
STANDARDIZED BIRTH PREVALENCE RATIOS FOR CENTRAL NERVOUS SYSTEM DEFECTS, CONGENITAL HEART DEFECTS, AND ALL ANOMALIES EXCEPT CNS AND CHD DEFECTS, PICKERING AND NEARBY COUNTIES (1973–1988)
REFERENCE = ONTARIO

CENTRAL NERVOUS SYSTEM DEFECTS

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	350	336.7	1.04	0.93	1.15
MARKHAM	37	54.1	0.68	0.48	0.94
PICKERING	30	36.4	0.82	0.56	1.18
AJAX	29	28.9	1.00	0.67	1.44
WHITBY	29	30.9	0.94	0.63	1.35
OSHAWA	126	103.6	1.22	1.01	1.45

CONGENITAL HEART DEFECTS

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	692	552.9	1.25	1.16	1.35
MARKHAM	88	91.4	0.96	0.77	1.19
PICKERING	63	61.8	1.02	0.78	1.31
AJAX	57	50.5	1.13	0.86	1.46
WHITBY	63	52.1	1.21	0.93	1.55
OSHAWA	237	168.3	1.41	1.23	1.60

ALL ANOMALIES EXCEPT CNS AND CHD DEFECTS

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	4034	3411.6	1.18	1.15	1.22
MARKHAM	617	557.1	1.11	1.02	1.20
PICKERING	377	383.5	0.98	0.89	1.09
AJAX	312	311.9	1.00	0.89	1.12
WHITBY	306	324.5	0.94	0.84	1.05
OSHAWA	1145	1040.9	1.10	1.04	1.17

TABLE 2.2
STANDARDIZED MORTALITY RATIOS FOR FATALITIES WITH BIRTH DEFECT, PICKERING AND NEARBY COUNTIES (1973–1988)
REFERENCE = ONTARIO

FATALITIES WITH ANY DEFECT

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	690	704.6	0.98	0.91	1.06
MARKHAM	111	113.3	0.98	0.81	1.18
PICKERING	69	77.4	0.89	0.69	1.13
AJAX	61	61.9	0.99	0.75	1.27
WHITBY	67	65.8	1.02	0.79	1.29
OSHAWA	221	216.3	1.02	0.89	1.17

FATALITIES WITH CENTRAL NERVOUS SYSTEM DEFECT

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	84	100.1	0.84	0.67	1.04
MARKHAM	12	15.8	0.76	0.39	1.33
PICKERING	7	10.8	0.65	0.26	1.33
AJAX	6	8.5	0.71	0.26	1.53
WHITBY	6	9.2	0.66	0.24	1.42
OSHAWA	37	31.0	1.19	0.84	1.64

FATALITIES WITH CONGENITAL HEART DEFECT

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED		LOWER	UPPER
SCARBOROUGH	98	116.6	0.84	0.68	1.02
MARKHAM	18	18.9	0.95	0.57	1.51
PICKERING	10	12.6	0.80	0.38	1.46
AJAX	9	10.0	0.90	0.41	1.70
WHITBY	11	10.7	1.02	0.51	1.83
OSHAWA	33	35.8	0.92	0.64	1.30

Table 3.1 Major Birth Defect Category Relative Risks in Relation to Monthly Tritium Release Levels During a 4-Month Window Corresponding with the First Trimester of Pregnancy

PICKERING

OUTCOME		ALL ANOMALIES				CNS				CHD				OTHER			
TRITIUM RELEASE TO*		WATER		AIR		WATER		AIR		WATER		AIR		WATER		AIR	
MEASURE**		AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH
Lowest	1	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
	2	1.04	0.95	0.96	0.71	0.68	0.48	1.17	0.56	2.06	1.49	0.84	0.84	1.04	0.86	0.94	0.68
RELEASE LEVEL***	3	1.08	0.92	0.88	0.92	0.85	0.90	1.29	1.43	1.99	1.48	0.58	0.77	0.97	0.78	0.92	0.95
	4	0.96	0.81	0.90	0.74	0.69	0.42	0.00	0.29	2.09	0.36	0.61	0.58	0.89	0.77	0.99	0.80
Highest	5	0.84	0.92	1.26	1.24	0.41	0.73	2.98	4.01	1.14	1.17	1.76	2.14	0.76	0.84	1.22	1.25

AJAX

OUTCOME		ALL ANOMALIES				CNS				CHD				OTHER			
TRITIUM RELEASE TO*		WATER		AIR		WATER		AIR		WATER		AIR		WATER		AIR	
MEASURE**		AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH
Lowest	1	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
	2	0.68	0.76	0.97	0.90	0.43	0.38	1.34	1.09	0.68	0.87	1.00	0.72	0.68	0.71	0.93	0.84
RELEASE LEVEL***	3	0.83	0.84	0.78	0.90	0.47	0.67	0.56	1.09	1.14	0.91	1.19	0.76	0.80	0.80	0.78	0.91
	4	0.83	0.80	1.04	1.04	0.37	0.34	0.22	0.59	1.15	0.94	0.70	0.95	0.80	0.80	1.17	1.13
Highest	5	0.73	0.77	0.87	0.79	0.62	0.75	0.99	0.89	0.90	1.04	1.73	1.15	0.75	0.78	0.91	0.72

* Tritium Release -- Water: To Lake Ontario in power plant cooling water
Air: Tritium releases to the atmosphere

** Measure-- Avg: Monthly tritium releases averaged over a 4-month period
High: The highest monthly release level during a 4-month period

*** Release Levels-- 1 - Lowest 25% of 4-month release levels
2 - Releases 25-49%
3 - Releases 50-74%
4 - Releases 75-87.5%
5 - Highest 12.5% of 4-month release values

Table 3.2 Major Birth Defect Category Relative Risks in Relation to Monthly Tritium Ground Monitored Levels During a 4-Month Window Corresponding with the First Trimester of Pregnancy

PICKERING

OUTCOME		ALL ANOMALIES		CNS		CHD		OTHER		DOWN SYNDROME	
MONITORING STATION*		HW1-3*		HW1-3		HW1-3		HW1-3		HW1-3	
MEASURE***		AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH
Lowest	1	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
	2	0.88	0.78	0.93	0.42	0.93	0.75	0.83	0.77	0.53	0.68
MONITORED LEVEL****	3	0.85	0.81	0.70	0.60	1.11	1.23	0.75	0.74	0.43	0.46
	4	1.00	0.89	0.95	0.60	1.29	0.95	0.95	0.81	0.69	0.73
Highest	5	0.97	0.79	0.62	1.00	1.00	1.08	0.83	0.61	1.03	0.98

AJAX

OUTCOME		ALL ANOMALIES		CNS		CHD		OTHER		DOWN SYNDROME	
MONITORING STATION**		HW4-5**		HW4-5		HW4-5		HW4-5		HW4-5	
MEASURE***		AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH	AVG	HIGH
Lowest	1	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
	2	1.21	1.23	0.76	0.54	0.99	1.01	1.03	1.26	0.99	0.80
MONITORED LEVEL****	3	1.20	1.17	1.19	0.66	1.27	1.27	1.00	1.06	0.88	1.50
	4	1.15	1.07	0.35	0.70	1.73	1.05	0.99	1.08	0.72	0.00
Highest	5	1.10	1.04	0.54	0.24	0.96	1.18	1.03	1.08	1.60	3.00

* Health & Welfare monitoring stations 1+2+3

** Health & Welfare monitoring stations 4+5

*** Measure-- Avg: Monthly tritium monitored averaged over a 4-month period
High: The highest monthly monitored level during a 4-month period

**** Monitored Levels-- 1 - Lowest 25% of 4-month monitored levels
2 - 25-49%
3 - 50-74%
4 - 75-87.5%
5 - Highest 12.5% of 4-month monitored levels

Table 4: Central Nervous System Defects Risk in Pickering 1973–1988
by Airborne Tritium Release (4 month high, lagged 9 months, 5 levels)
Stratified by Surveillance System

					95% CONFIDENCE INTERVAL	
		LIVEBIRTHS	CASES	ODDS RATIO	Lower	Upper
RELEASE LEVEL	1	3617	9	1.00	--	--
	2	2985	4	.56	.18	1.97
	3	2676	9	1.43	.45	3.58
	4	1662	1	.29	.02	2.06
	5	938	6	4.01	1.25	14.04

Test for trend: 1.67 p= .197

TABLE 5.1
STANDARDIZED BIRTH PREVALENCE RATIOS BY BIRTH DEFECT CATEGORY, PICKERING (1973–1988)
REFERENCE = ONTARIO

CATEGORIES	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
	OBSERVED	EXPECTED*		LOWER	UPPER
Cases	379	382.9	0.99	0.89	1.09
All anomalies	491	508.9	0.96	0.88	1.05
Central nervous system	30	36.4	0.82	0.56	1.18
Anencephalus & similar anomalies	1	5.3	0.19	0.00	0.95
Spina bifida	9	10.1	0.89	0.41	1.69
Microcephalus & brain reduction	6	6.2	0.96	0.35	2.08
Congenital hydrocephalus	6	10.4	0.58	0.21	1.25
Eye anomalies	5	6.6	0.76	0.24	1.75
Ear, face & neck anomalies	16	12.5	1.28	0.73	2.08
Congenital heart defects	63	61.8	1.02	0.78	1.31
Ventricular septal defect	24	23.2	1.03	0.66	1.54
Circulatory system anomalies	34	25.3	1.34	0.93	1.88
Respiratory system anomalies	12	11.6	1.04	0.54	1.81
Cleft lip and/or palate	16	18.2	0.88	0.50	1.43
Digestive system anomalies	53	53.2	1.00	0.75	1.30
Genital organ anomalies	35	34.0	1.03	0.72	1.43
Urinary system anomalies	14	15.6	0.90	0.49	1.50
Musculoskeletal anomalies	137	150.7	0.91	0.76	1.08
Congenital dislocation of hip	37	40.5	0.91	0.64	1.26
Clubfoot	37	48.8	0.76	0.53	1.04
Limb reduction deformities	5	4.4	1.14	0.37	2.64
Down syndrome **	24	12.9	1.85	1.19	2.76
Other chromosomal anomalies	4	4.6	0.86	0.23	2.18
Other & unspecified anomalies	16	19.2	0.83	0.48	1.35

* Adjusted for year of birth

** Adjusted for year of birth and mother's age

TABLE 5.2
STANDARDIZED BIRTH PREVALENCE RATIOS BY BIRTH DEFECT CATEGORY, AJAX (1973–1988)
REFERENCE = ONTARIO

	FREQUENCY		OBS/EXP	95% CONFIDENCE INTERVAL	
CATEGORIES	OBSERVED	EXPECTED*		LOWER	UPPER
Cases	315	310.8	1.01	0.90	1.13
All anomalies	426	413.4	1.03	0.93	1.13
Central nervous system	29	28.9	1.00	0.67	1.44
Anencephalus & similar anomalies	2	4.1	0.49	0.06	1.71
Spina bifida	8	7.9	1.01	0.43	1.98
Microcephalus & brain reduction	3	5.0	0.60	0.12	1.72
Congenital hydrocephalus	10	8.2	1.22	0.59	2.25
Eye anomalies	5	5.3	0.94	0.30	2.17
Ear, face & neck anomalies	17	10.0	1.70	0.99	2.72
Congenital heart defects	57	50.5	1.13	0.86	1.46
Ventricular septal defect	25	19.1	1.31	0.85	1.93
Circulatory system anomalies	26	20.6	1.26	0.82	1.85
Respiratory system anomalies	6	9.5	0.63	0.23	1.37
Cleft lip and/or palate	6	14.5	0.41	0.15	0.90
Digestive system anomalies	41	42.7	0.96	0.69	1.30
Genital organ anomalies	20	27.4	0.73	0.45	1.13
Urinary system anomalies	18	13.0	1.38	0.82	2.19
Musculoskeletal anomalies	120	123.1	0.97	0.81	1.17
Congenital dislocation of hip	27	33.7	0.80	0.53	1.17
Clubfoot	29	39.3	0.74	0.49	1.06
Limb reduction deformities	6	3.5	1.71	0.63	3.71
Down syndrome **	14	9.6	1.46	0.80	2.44
Other chromosomal anomalies	4	3.8	1.05	0.28	2.67
Other & unspecified anomalies	17	15.8	1.08	0.63	1.72

* Adjusted for year of birth

** Adjusted for year of birth and mother's age

Table 6 Down Syndrome Risk in Pickering 1973–1988 by Airborne Tritium Release (4 month high, lagged 9 months, 5 levels) Stratified by Surveillance System

		LIVEBIRTHS	CASES	ODDS RATIO	95% CONFIDENCE INTERVAL	
					Lower	Upper
RELEASE LEVEL	1	3616	10	1.00	--	--
	2	2987	2	.30	.05	1.51
	3	2681	4	.66	.21	2.32
	4	1662	1	.12	.01	1.73
	5	938	6	2.72	.59	9.52

Test for trend: .53 p= .468

Table 7 Down Syndrome Risk in Ajax 1973–1988 by Monthly Airborne Tritium Levels as measured by Health & Welfare Ground Monitoring Stations 4 and 5 combined (4 month high, lagged 9 months, 5 levels) Stratified by Surveillance System

		LIVEBIRTHS	CASES	ODDS RATIO	95% CONFIDENCE INTERVAL	
					Lower	Upper
MONITORED TRITIUM LEVEL	1	1392	2	1.00	--	--
	2	1849	3	0.79	.09	7.91
	3	2334	5	1.50	.23	10.49
	4	1307	0	.00	?	?
	5	1324	7	3.00	.47	20.97

Test for trend: 1.16 p= .282

TABLE 8 CALCULATION OF EXPECTED DOWN SYNDROME CASES FOR PICKERING AND AJAX

	Age of Mother								
	<20	20–24	25–29	30–34	35–39	40–44	45–49	Total Births	Expected Cases
DOWN SYNDROME RISK* per 1,000 Births	0.74	0.74	0.74	1.33	4.20	15.10	50.00		
LIVEBIRTH DISTRIBUTION									
Durham 1975 **	11.1%	30.8%	39.1%	14.9%	3.3%	0.9%	0.0%		
Pickering 78–88 ***	3.2%	17.7%	43.4%	28.8%	6.2%	0.6%	0.0%		
Ajax 1978–88 ***	3.0%	21.3%	46.7%	23.9%	4.6%	0.4%	0.0%		
EXPECTED CASES									
Pickering 73–77	0.19	0.54	0.68	0.47	0.33	0.31	0.00	2358	2.52
Pickering 78–88	0.20	1.13	2.76	3.30	2.27	0.78	0.00	8583	10.43
Ajax 73–77	0.13	0.37	0.47	0.32	0.22	0.21	0.00	1618	1.73
Ajax 78–88	0.16	1.13	2.48	2.29	1.39	0.43	0.00	7184	7.89
OBSERVED CASES 78–88								Age Known Total	Observed Total
Pickering 78–88	0	3	4	7	1	1	0	16	19
Ajax 78–88	0	0	4	3	1	1	0	9	13

* Data from Hook, E.B., Lindsjo, A., American Journal of Human Genetics, Volume 30, 1978:19–27; Trimble, B.K., Baird, P., American Journal of Medical Genetics, Volume 2, 1978:1–5; and Christianson, R.E., The Lancet, Volume 2, 1976:1198.

** Maternal Age distribution from Vital Statistics Volume 1, Statistics Canada 1975.

*** Maternal age distribution from HMRI delivery records 1978–1988

Figure 1. Pickering Area Birth Defects & Infant Mortality Study Strategy

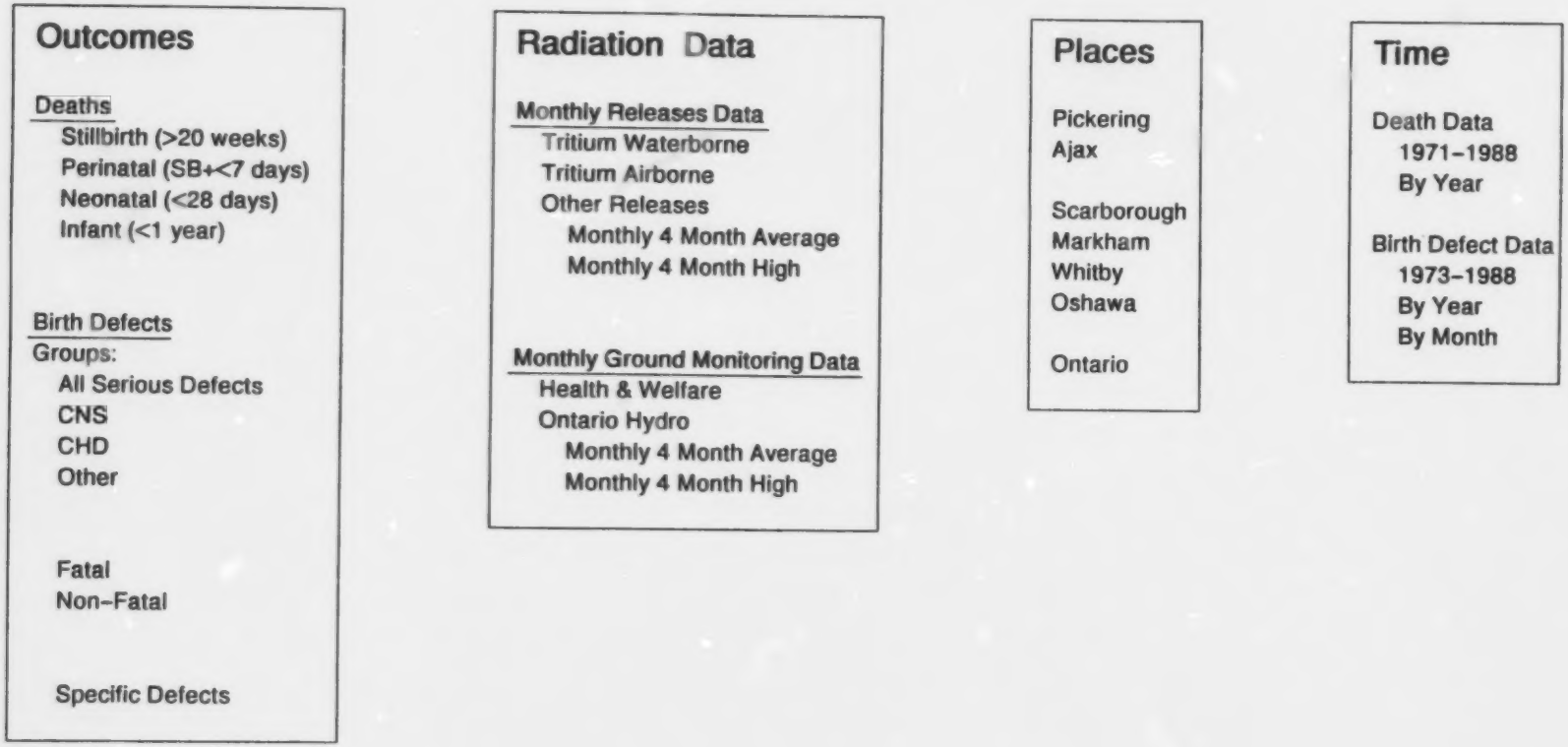


Figure 2. PICKERING NGS
TRITIUM MONTHLY RELEASES

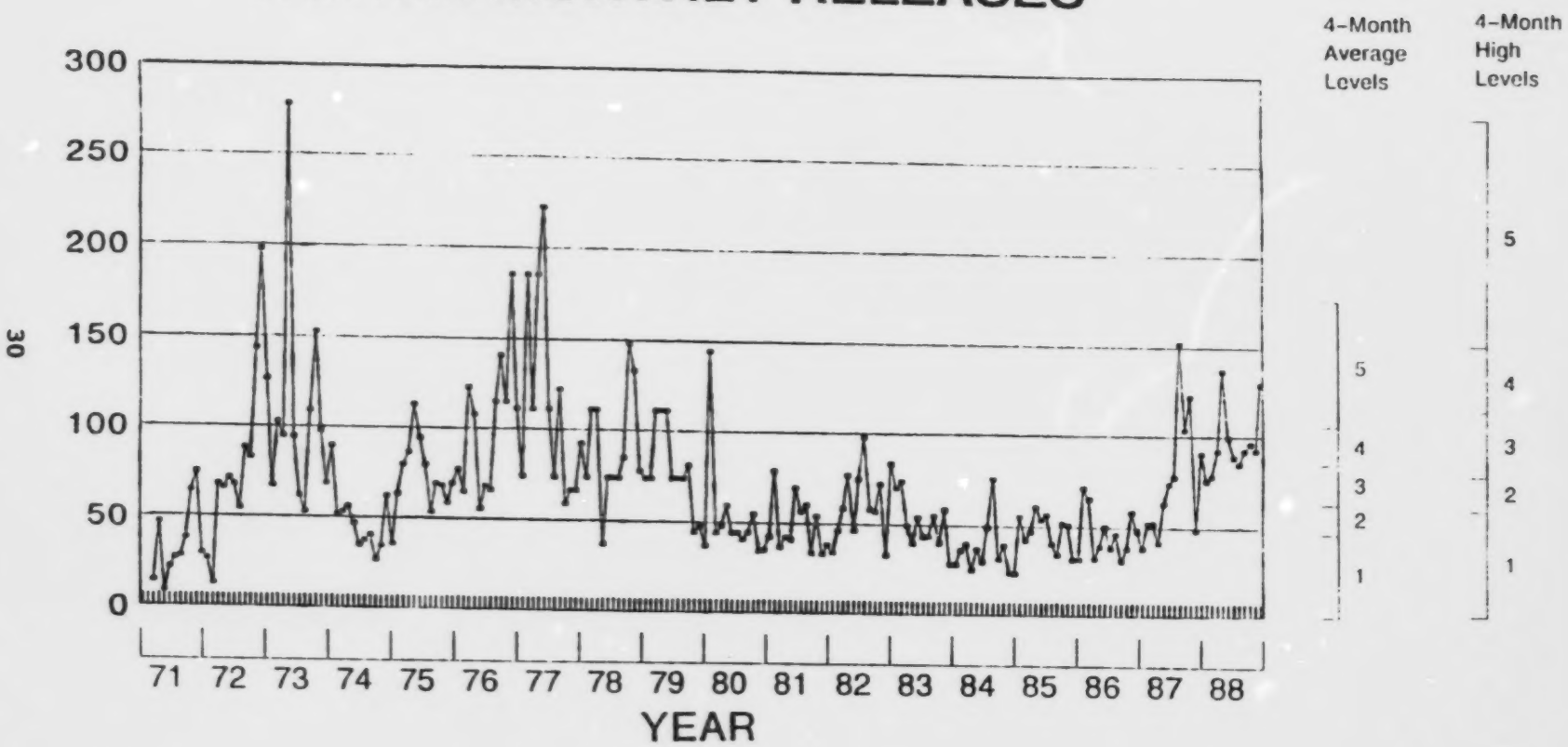


Figure 3. PICKERING NGS
TRITIUM MONTHLY RELEASES

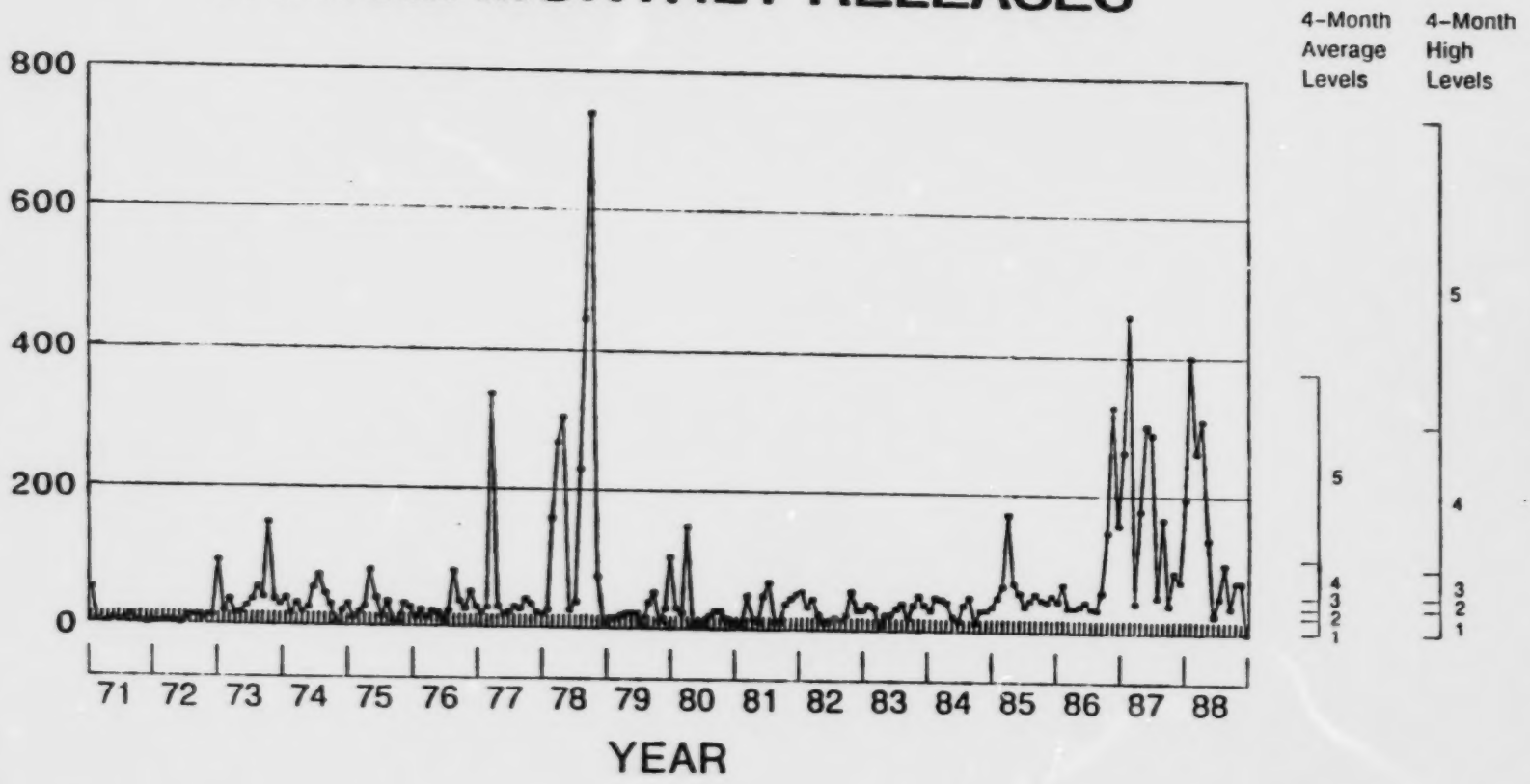
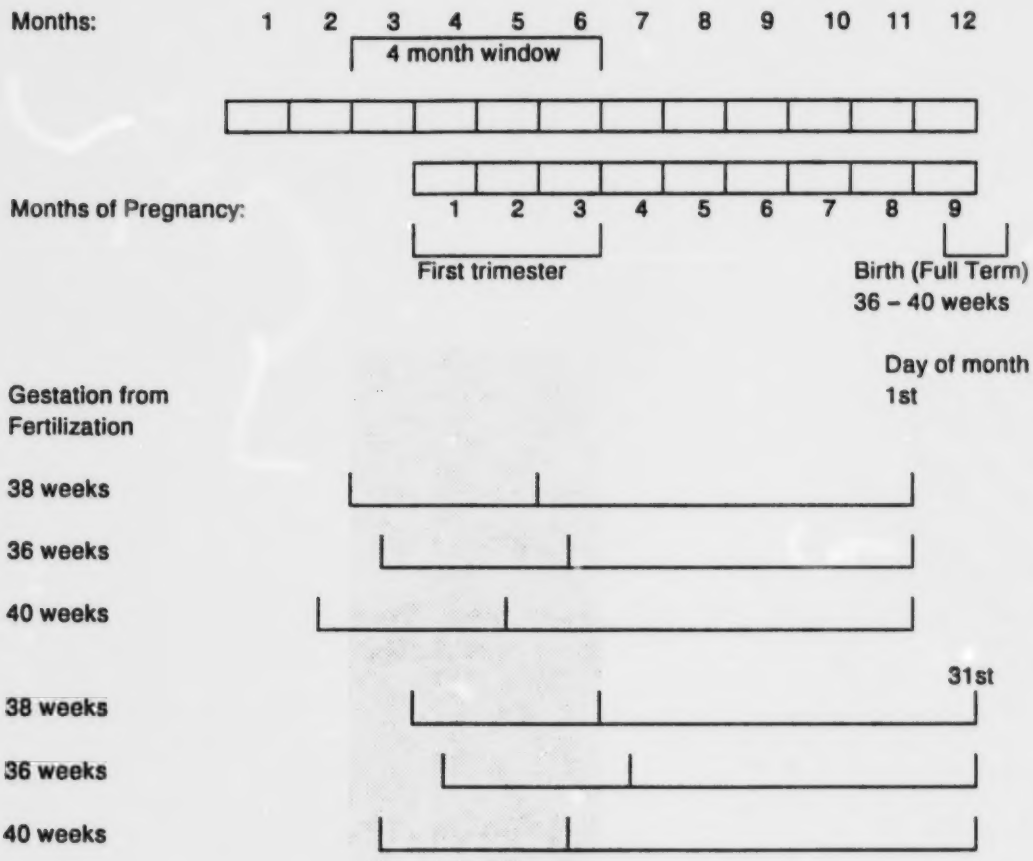
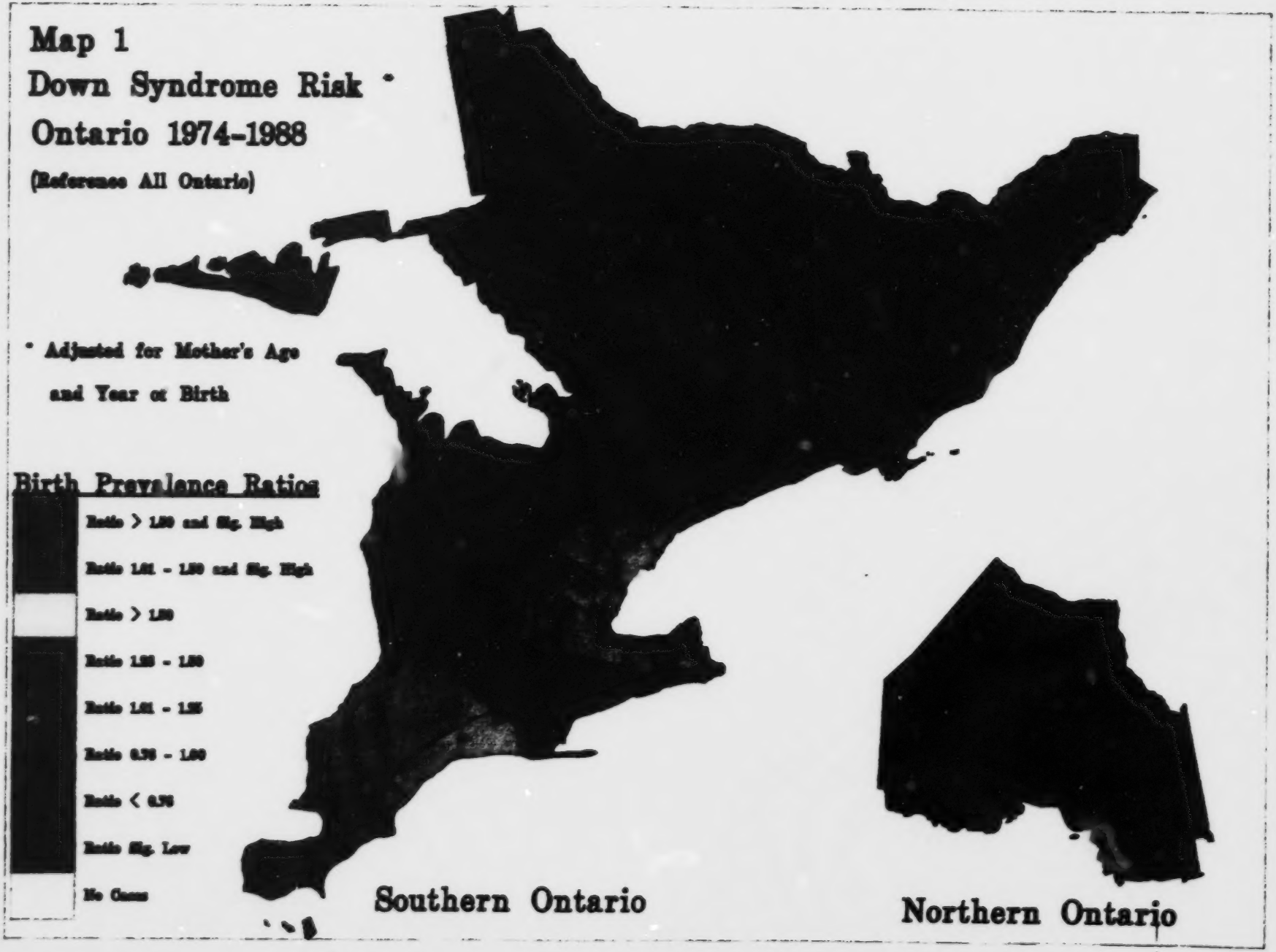
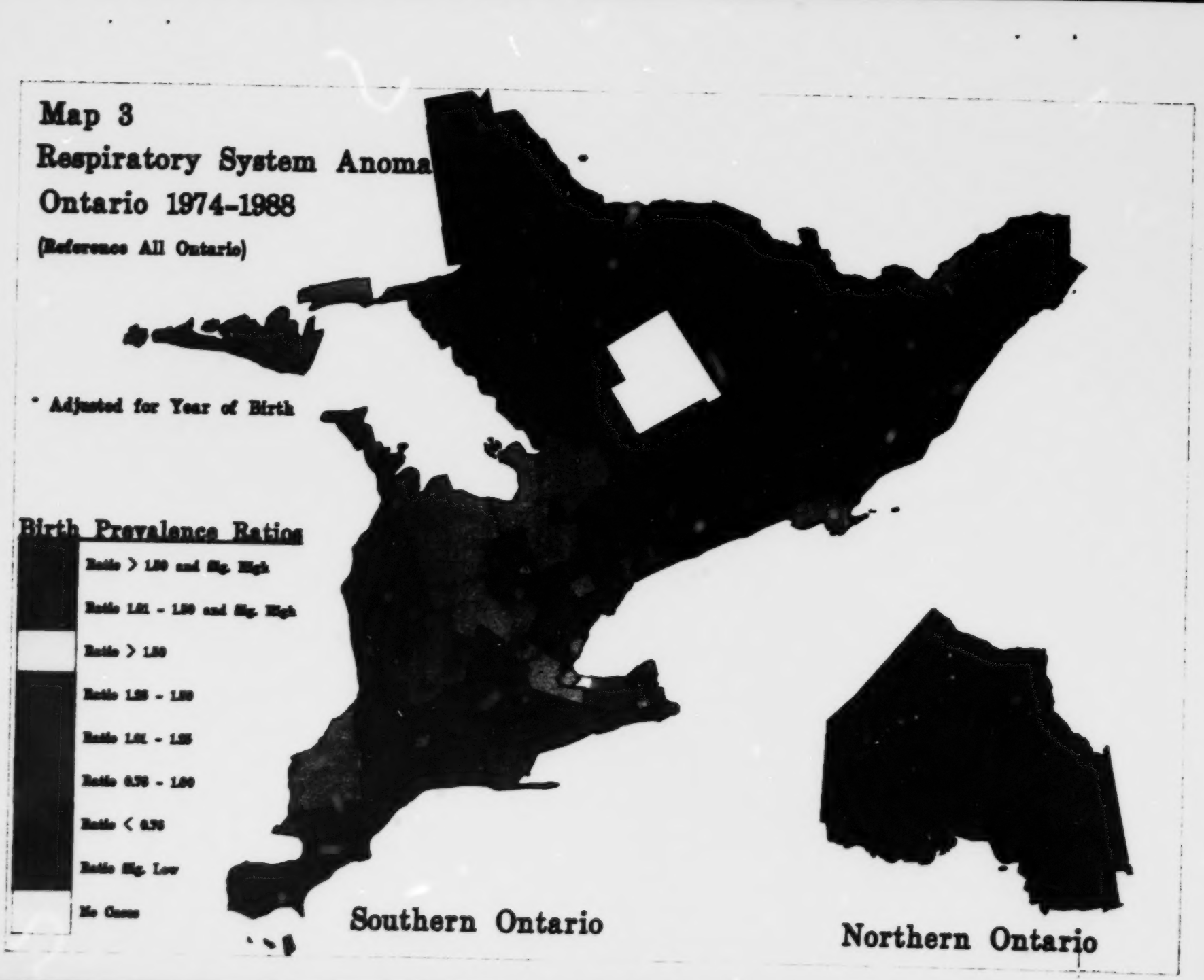


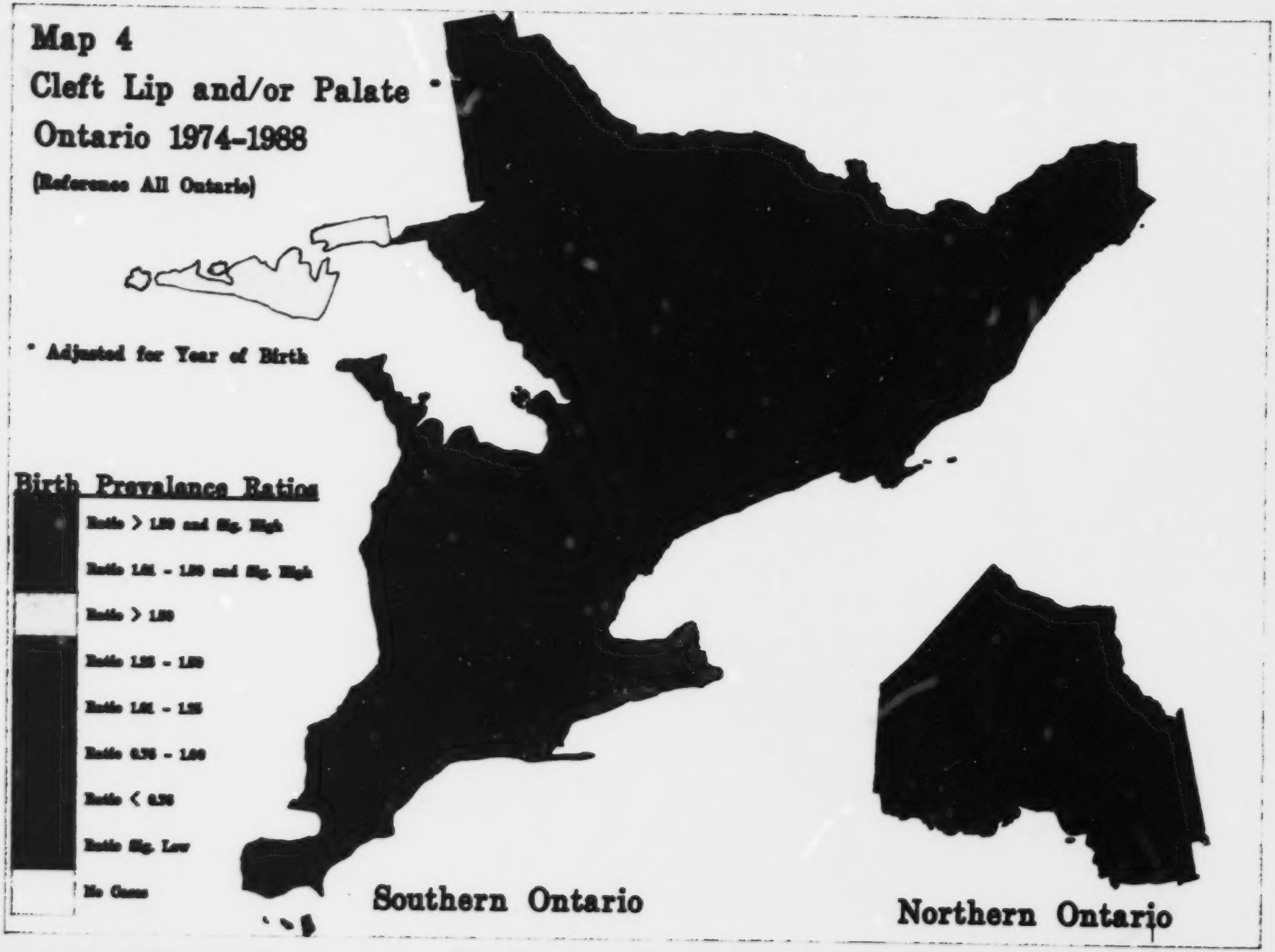
Figure 4. Lagging Exposure for First Trimester to Month of Birth




Map 1
Down Syndrome Risk *
Ontario 1974-1988
(Reference All Ontario)
* Adjusted for Mother's Age and Year of Birth
Birth Prevalence Ratios
Ratio > 1.50 and Sig. High
Ratio 1.51 - 1.50 and Sig. High
Ratio > 1.50
Ratio 1.25 - 1.50
Ratio 1.01 - 1.25
Ratio 0.76 - 1.00
Ratio < 0.76
Ratio Sig. Low
No Cases
Southern Ontario
Northern Ontario

Map 2
Spina Bifida Risk *
Ontario 1974-1988
(Reference All Ontario)
* Adjusted for Year of Birth
Birth Prevalence Ratios
Ratio > 1.50 and Sig. High
Ratio 1.01 - 1.50 and Sig. High
Ratio > 1.50
Ratio 1.26 - 1.50
Ratio 1.01 - 1.25
Ratio 0.76 - 1.00
Ratio < 0.76
Ratio Sig. Low
No Cases
Southern Ontario
Northern Ontario


Map 3
Respiratory System Anoma
Ontario 1974-1988
(Reference All Ontario)
* Adjusted for Year of Birth
Birth Prevalence Ratios
Ratio > 1.50 and Sig. High
Ratio 1.01 - 1.50 and Sig. High
Ratio > 1.50
Ratio 1.25 - 1.50
Ratio 1.01 - 1.25
Ratio 0.76 - 1.00
Ratio < 0.76
Ratio Sig. Low
No Cases
Southern Ontario
Northern Ontario


Map 4
Cleft Lip and/or Palate *
Ontario 1974-1988
(Reference All Ontario)
* Adjusted for Year of Birth
Birth Prevalence Ratios
Ratio > 1.50 and Sig. High
Ratio 1.01 - 1.50 and Sig. High
Ratio > 1.50
Ratio 1.25 - 1.50
Ratio 1.01 - 1.25
Ratio 0.76 - 1.00
Ratio < 0.76
Ratio Sig. Low
No Cases
Southern Ontario
Northern Ontario

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Finally, the advice and carefully considered comments of the expert committee, Dr. L. McIntyre, Dr. J.N. Yamazaki, Dr. R.L. Brent, Dr. T.V.N. Persaud, Dr. W.J. Schull, Dr. C. Brisson, Dr. G.B. Hill, and Dr. G. Howe, have been invaluable.

APPENDIX A

DEFINITIONS

Stillbirth: fetal deaths of 20 or more weeks gestation.

Stillbirth Rate: number of stillbirths per 1,000 live births and stillbirths.

Perinatal Death: fetal deaths of 28 or more weeks' gestation plus infant deaths under 7 days (1 week) of age.

Perinatal Death Rate: number of perinatal deaths per 1,000 stillbirths (> = 28 weeks) plus live births.

Infant Death: deaths under 1 year of age.

Infant Death Rate: number of deaths under 1 year of age per 1,000 live births.

Neonatal Death: infant deaths up to 28 days of age.

Neonatal Death Rate: number of neonatal deaths per 1,000 live births.

Birth Defect Case Definition:

Cases were defined on the basis of the International Classification of Disease - 9th Revision[1] (ICD-9) rubrics. Classifications 740-759.9 (congenital anomalies) were included, with some specific diagnoses excluded.

Undescended testes, skin tags and birth marks were not included, since in general they can be considered normal variants.[2] The conditions are common and generally medically unimportant. High variability in reporting of these conditions can mask important variation in less common but more important conditions. The definition applies to case and all anomaly rates. Patent ductus arteriosus has also been removed because it often occurs as a consequence of prematurity in which case it is not a defect. (Gestational age is unavailable in the HMRI dataset so premature infants cannot be identified to distinguish which patent ductus cases should be considered birth defects.)

Case Rate: number of children with birth defects/10,000 live births.

Anomaly Rate: total number of birth defects reported/10,000 live births.

Specific Birth Defect Rates: count of a specific birth defect/10,000 live births+stillbirths.

Central Nervous System (CNS) Defects:

The CNS category includes all defects coded under ICD-9 codes:
740 - Annencephalus and similar anomalies
741 - Spina bifida
742 - Other Congenital Anomalies of the nervous system (includes hydrocephalus and microcephalus).

Congenital Heart Defects (CHD)

The CHD category includes all defects coded under ICD-9 codes: 745-747.

Non CNS/CHD Anomalies

All defects except CNS and CHD anomalies, i.e., ICD-9 codes: 743-744 and 748-759.

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BIRTH DEFECT CATEGORIES AND ICD-9 CODES

BIRTH DEFECT CATEGORY*	ICD-9 CODE(S)
Cases	740.0–759.9
All anomalies	740.0–759.9
Central nervous system	740.0–742.9
Anencephalus & similar anomalies	740.0–740.2
Spina bifida	741.0–741.9
Microcephalus & brain reduction	742.1–742.2
Congenital hydrocephalus	742.3
Eye anomalies	743.0–743.9
Ear, face & neck anomalies	744.0–744.9
Congenital heart defects	745.0–746.9
Ventricular septal defect	745.4
Circulatory system anomalies	747.1–747.9
Respiratory system anomalies	748.0,.1,.2,.3,.4,.5,.6,.8,.9
Cleft lip and/or palate	749.0–749.2
Digestive system anomalies	750.1–751.9
Genital organ anomalies	752.0–752.9
Urinary system anomalies	753.0–753.9
Musculoskeletal anomalies	754.0–754.8;755.0–756.9
Congenital dislocation of hip	754.3
Clubfoot	754.5–754.7
Limb reduction deformities	755.2–755.3
Down syndrome	758.0
Other chromosomal anomalies	758.1–758.8
Other & unspecified anomalies	757.0–757.9;758.9;759.0–759.9

* Major category at left margin, important subcategories indented.

APPENDIX B

CANADIAN CONGENITAL ANOMALIES

SURVEILLANCE SYSTEM (CCASS)

The CCASS database is used to monitor the incidence of birth defects in Canada and to serve as starting point for undertaking epidemiologic research studies. Between 1966 and 1986 participating provinces (New Brunswick, Manitoba, Alberta and B.C. since 1966, Ontario since 1973, and PEI since 1977) provided information concerning children with birth defects noted during the first year of life.

Sources of information varied by province and time period, but the key sources were generally Physicians Notice of Live Birth or Stillbirth and hospital admission/discharge summaries. Data collected on each child included: the infants name, date of birth, nature of the defect (4 digit ICD-8 codes or a written description before 1980, 4 digit ICD-9 codes since 1980), parent's names, mother's age, municipality of residence and sometimes a provincial health registration number.

Since 1987, surveillance in all provinces except Alberta has been based on hospital admission/discharge summary data reported to the Hospital Medical Records Institute (HMRI) or Manitoba's Hospital Services Commission. In Ontario, HMRI coverage of all public hospitals began in 1978. A number of other provinces have approached full provincial coverage through the 1980's.

The decision to switch to HMRI-based surveillance was three fold. First, an analysis of the contribution of different data sources to defect rates in CCASS demonstrated that ascertainment of the vast majority of birth defects included a hospitalization. Second, using HMRI data exclusively would improve the cross-province comparability of the data. Third, there would be a substantial reduction in resources required to run the system, freeing resources to do more analytic surveillance research. (Internal Report -Johnson, K.C., The Feasibility of Using HMRI Hospital Data for Birth Defect Surveillance in Canada, January 1990.)

Birth defect surveillance in Ontario from 1978 onward is based exclusively on data from HMRI. The decision to use HMRI-based reporting exclusively was the result of the problems with reporting experienced with the old system in Ontario in the late 1970's and early 1980's. Changes in the availability of hospital data (at that time reported through the Ontario Hospital Insurance Program) resulted in large variations in defect rates in different time periods.

The Laboratory Centre for Disease Control receives HMRI data yearly on compact disk. The disk contains one 317 character record for every hospital admission in a hospital using HMRI's services in Canada in the most recent fiscal year. The database does not contain names or addresses. Each record does include: provincial health care number, institution number and chart number (each systematically scrambled), 6 digit residence code and/or postal code, up to 15 four digit ICD-9 diagnostic codes, hospital admission date, date of birth, sex, age, and vital status.

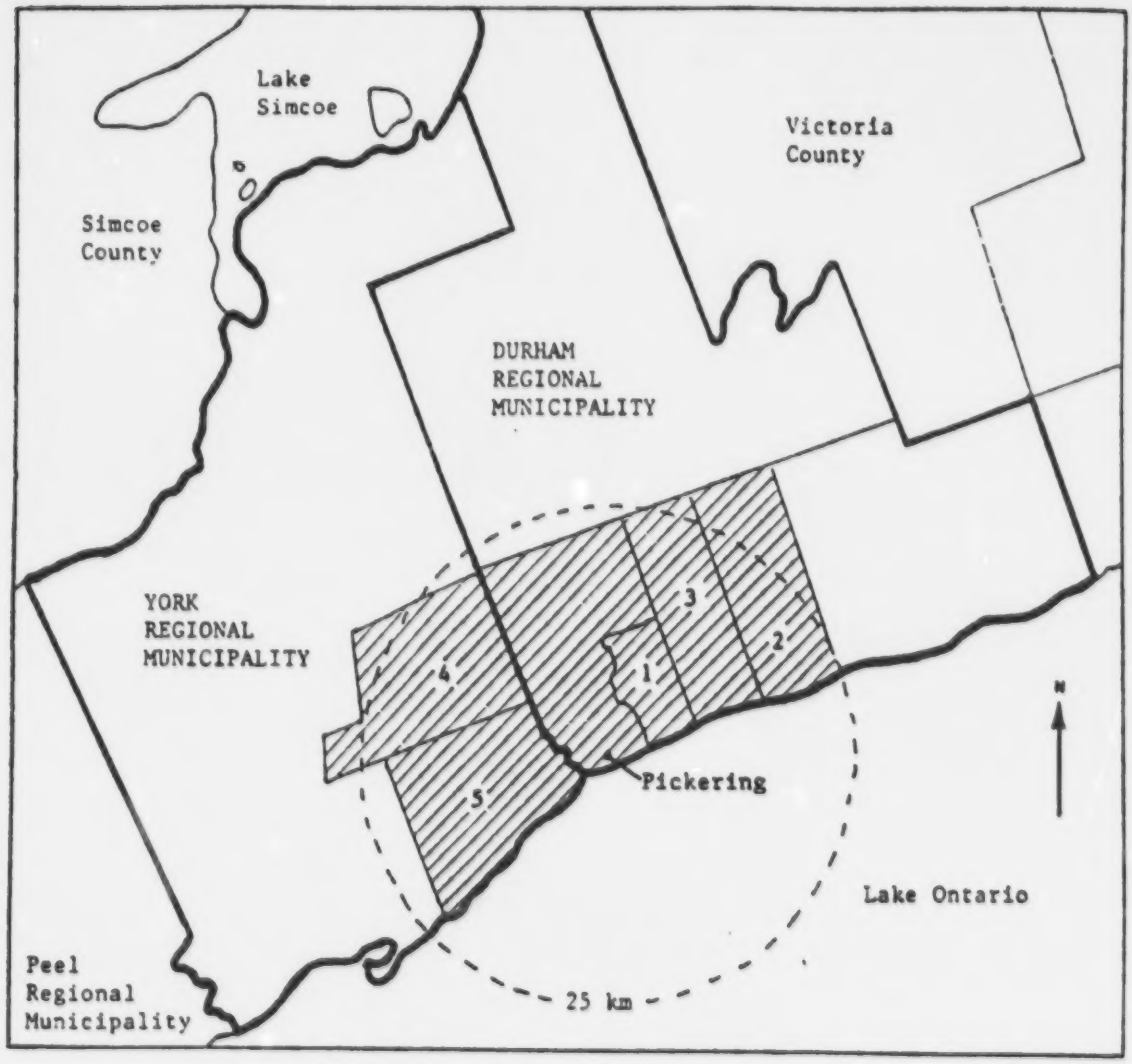
Records with an admission date during the first two years of life and a discharge diagnosis for a birth defect (congenital anomaly) (International Classification of Disease, Ninth Revision, (ICD-9) codes 740.0 to 759.9) are selected. (We generally restrict analysis to one year followup to make the analysis more timely, i.e. we have final numbers a year earlier, but select admissions up to two years for special followup). An automated two step record-linkage process is used to resolve multiple admissions and coding conflict between different records concerning the same child. The data pertaining to births in one province in one year are first sorted by the hospital insurance number. Records with matching hospital insurance numbers are melded together (unless a multiple pregnancy is indicated, where the meld decision is based on other criteria). A second pass of the merged dataset is performed after sorting on date of birth. All records where the date of birth and sex of the child are the same are compared for identifying information including OHIP number, residence code and/or postal code and consolidated where agreement and disagreement weights (established and optimised for each of the variables for each province) meet certain criteria.

The melding process includes not only removal of duplicates and redundancies but also the detection and resolution of contradictions in diagnostic codes. Over 300 resolution rules have been formulated and grouped into nine separate tables, each of which corresponds to a decision point in an algorithm which considers the number of digits of the ICD codes being compared, wether or not the conflicting codes come from the same or different records and the time sequence in which the diagnoses were made.

APPENDIX C

YORK AND DURHAM REGIONAL MUNICIPALITIES
(Pickering Nuclear Generating Station)

from: Standard Geographic Classification 1981, Volume 1A



		Population (1981)
	Pickering T	37754
1	Ajax T	25475
2	Oshawa C	117519
3	Whitby T	36698
4	Markham T	77037
5	Scarborough Bor	443353

Area of "Nearby" Analysis

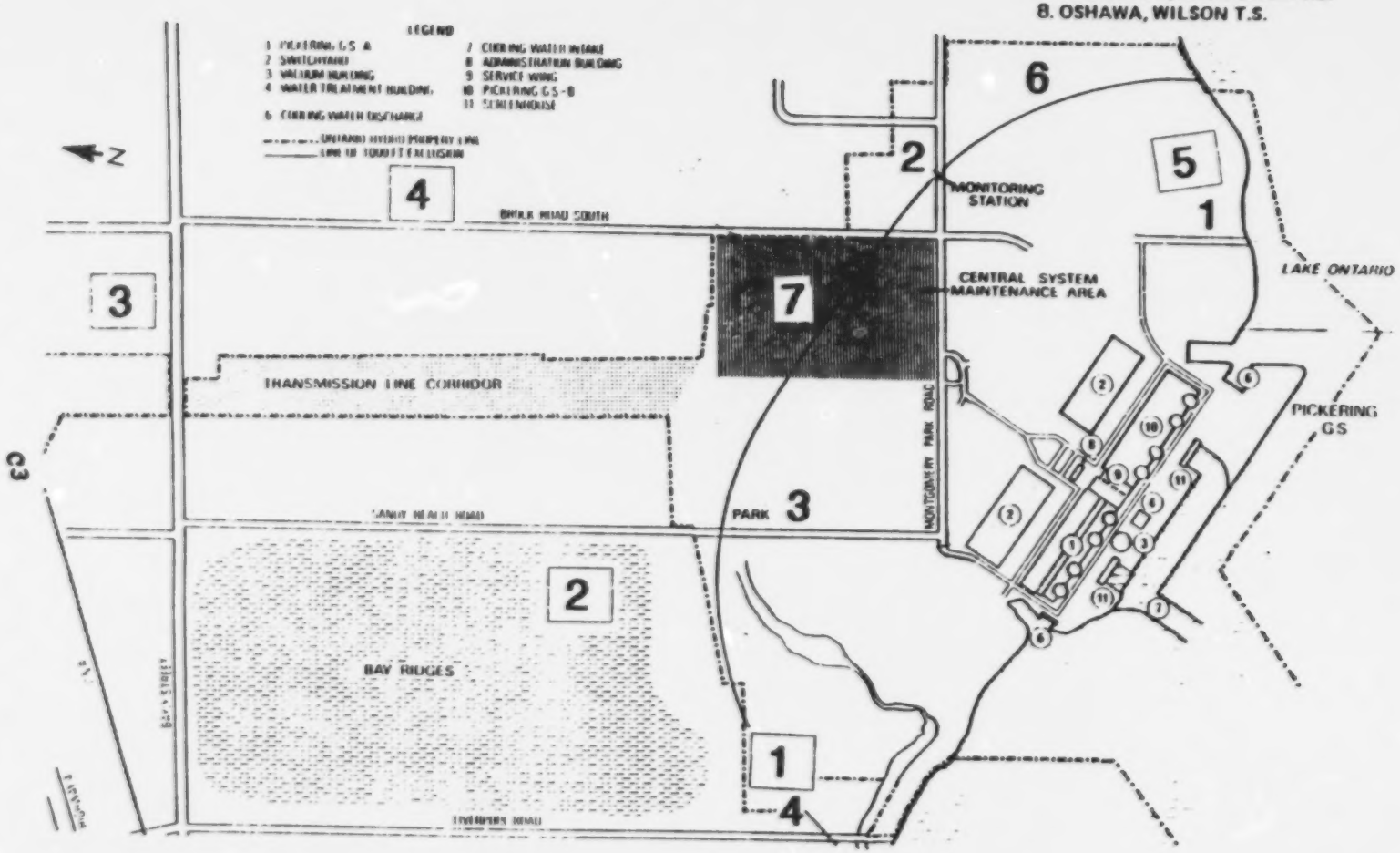
0 10 20 30 km

Dixie
Cherrywood
Cherrywood Station
CANADIAN PACIFIC
PICKERING
Dunbarton
Deckers Hill
Riverside
Heritage
AJAX
CN
401
Oak Grove
Squires Beach
Simcoe Point
Richer Power Plant
Moore Point
PETTICOAT CREEK
CONSERVATION AREA
LAKE ONTARIO
75.2±

C2

Control Sites:

5. HIGHWAY 7, BROUGHAM T.S.
8. OSHAWA, WILSON T.S.



PICKERING GS ENVIRONMENTAL MONITORING STATIONS

[1] HEALTH AND WELFARE
1 ONTARIO HYDRO

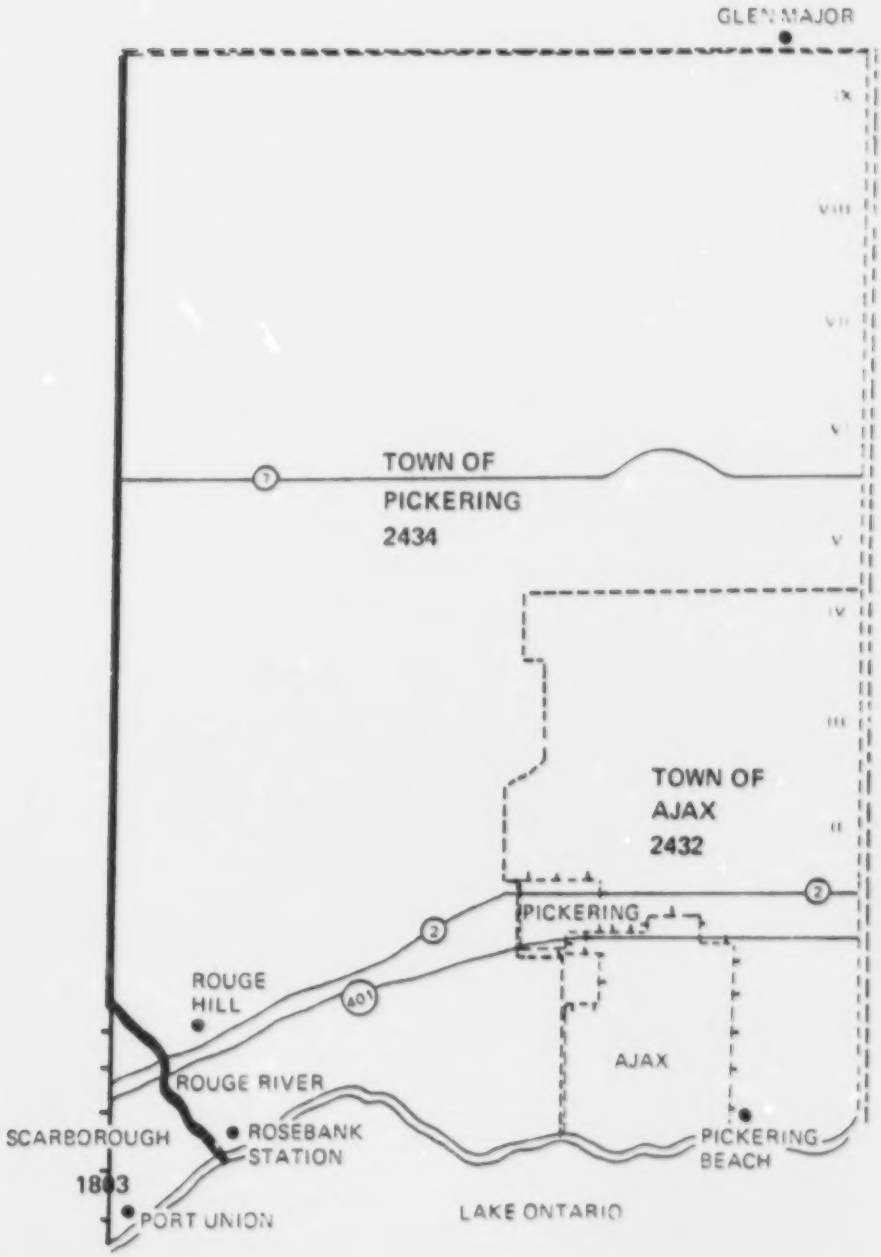
APPENDIX D

RESIDENCE CODES FOR AREA 'NEARBY' (25 KM. RADIUS)
PICKERING NUCLEAR GENERATING STATION
1971 - 1988

	Standard Geographic Classification (SGC)		Ontario Ministry of Health	
'Nearby' Area	1971 - 1973	1974 - 1986	1971-73	1974--->
Scarborough Bor.	20001	20001	1803	1803
Markham T.	19036	19036	3902	3902
Pickering T.	18001	18001	2407	2434
Ajax T.	18004 (Pickering Vl.) and 18002 (Ajax Vl.) amalgamated to become --->	18005 (Ajax T.)	2402	2432
Whitby T.	18009	18009	2404	2435
Oshawa C.	18012 (E. Whitby Twp.) and 18014 (Oshawa C.) amalgamated to become --->	18013 (Oshawa C.)	2401	2431

Please Note: The provincial code '35' for Ontario is the first two digits in front of all of the above Standard Geographic Codes

FORMER TOWNSHIP OF PICKERING



Legend

Old Boundaries		New Boundaries		Identifying Marks & Names
County		Regional		
Municipal		Municipal		

APPENDIX E

Distances (in km.) of Water Intakes and Urban Areas (1981) from Pickering NGS

	Distances to Water Intakes	Distances to Urban Areas		
		Minimum	Average	Maximum
Pickering 73–80*	1.1	1.6	3.2	5.6
80 + *	4.8 to 19.4			
Ajax	4.8	3.6	5.6	6.5
Whitby	12.9	10.5	12.9	16.9
Oshawa	19.4	16.1	19.4	23.4
Scarborough	**	4.8	16.1	21.0
Markham	**	14.5	16.9	19.4

* Pickering water treatment plant closed in November 1980
Water then came from Ajax, Whitby, and Oshawa

** Not on Lake Ontario

APPENDIX F

Table 1. Description of Analysis Variables for Tritium Emissions from Pickering NGS 1971–1988 (terabecquerels/month)

Waterborne 4 Month Averages

Level	Cummulative Percent	Sample Size	Minimum	Maximum	Average	Median
1	25.0%	48	1.7	22.6	14.4	17.0
2	50.0%	48	22.6	33.9	28.5	28.7
3	75.0%	48	34.2	49.4	41.3	40.7
4	87.5%	24	49.5	103.3	75.4	72.8
5	100.0%	24	117.5	371.8	218.9	203.5

Waterborne 4 Month Highs

Level	Cummulative Percent	Sample Size	Minimum	Maximum	Average	Median
1	25.0%	49	2.3	34.4	21.5	22.2
2	50.0%	47	35.8	50.7	43.7	44.4
3	75.0%	48	51.8	91.8	66.5	66.6
4	87.5%	25	103.6	299.7	178.9	159.1
5	100.0%	23	303.4	740.0	433.5	399.6

Airborne 4 Month Averages

Level	Cummulative Percent	Sample Size	Minimum	Maximum	Average	Median
1	25.0%	48	29.0	46.1	40.2	41.2
2	50.0%	48	46.3	62.3	51.7	50.8
3	75.0%	48	62.8	85.6	73.2	72.6
4	87.5%	24	86.0	106.4	95.1	93.3
5	100.0%	24	107.1	175.8	130.1	132.3

Airborne 4 Month Highs

Level	Cummulative Percent	Sample Size	Minimum	Maximum	Average	Median
1	25.0%	50	38.9	59.2	52.2	54.8
2	50.0%	46	60.3	77.7	70.1	71.3
3	75.0%	48	78.8	114.7	96.2	93.4
4	87.5%	26	122.1	151.7	136.9	141.8
5	100.0%	22	152.5	277.9	205.0	197.4

Table 2. Descriptions of Analysis Variables for Airborne Tritium Concentrations* as Measured at Health & Welfare Ground Monitoring Stations Near the Pickering NGS 1973–1988 (Becquerels/Cubic Metre Air)

Stations 1+2+3 4 Month Averages

Level	Sample Size	Average	Median	Minimum	Maximum
1	46	0.3	0.4	0.1	0.6
2	46	1.0	1.0	0.6	1.4
3	48	1.9	2.0	1.4	2.5
4	26	3.0	2.9	2.5	3.7
5	26	5.9	4.6	3.7	11.3

Stations 1+2+3 4 Month Highs

Level	Sample Size	Average	Median	Minimum	Maximum
1	47	0.7	0.6	0.2	1.1
2	45	1.7	1.8	1.1	2.2
3	44	3.2	3.1	2.2	4.0
4	29	5.1	4.7	4.4	5.9
5	27	14.6	11.2	6.2	30.1

Stations 4+5 4 Month Averages

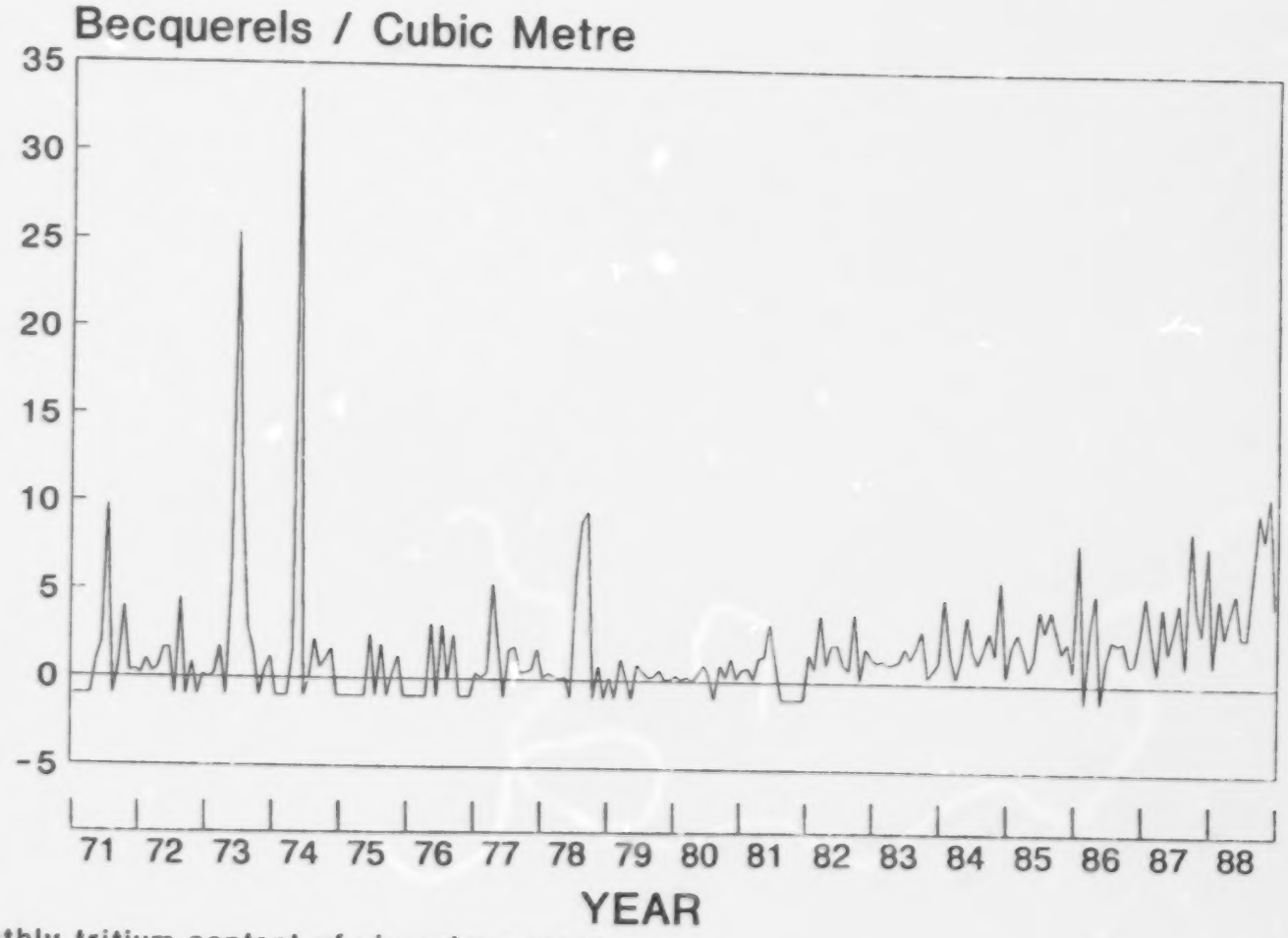
Level	Sample Size	Average	Median	Minimum	Maximum
1	38	1.2	1.1	0.6	1.8
2	50	2.9	3.0	1.9	3.9
3	52	5.3	5.1	4.0	7.1
4	26	9.7	10.0	7.4	12.4
5	26	15.2	14.5	12.4	22.0

Stations 4+5 4 Month Highs

Level	Sample Size	Average	Median	Minimum	Maximum
1	40	2.3	2.2	0.9	3.9
2	48	5.7	5.5	3.9	7.9
3	55	11.0	10.9	8.3	15.6
4	21	18.7	18.6	16.6	21.1
5	28	30.0	28.6	24.6	38.5

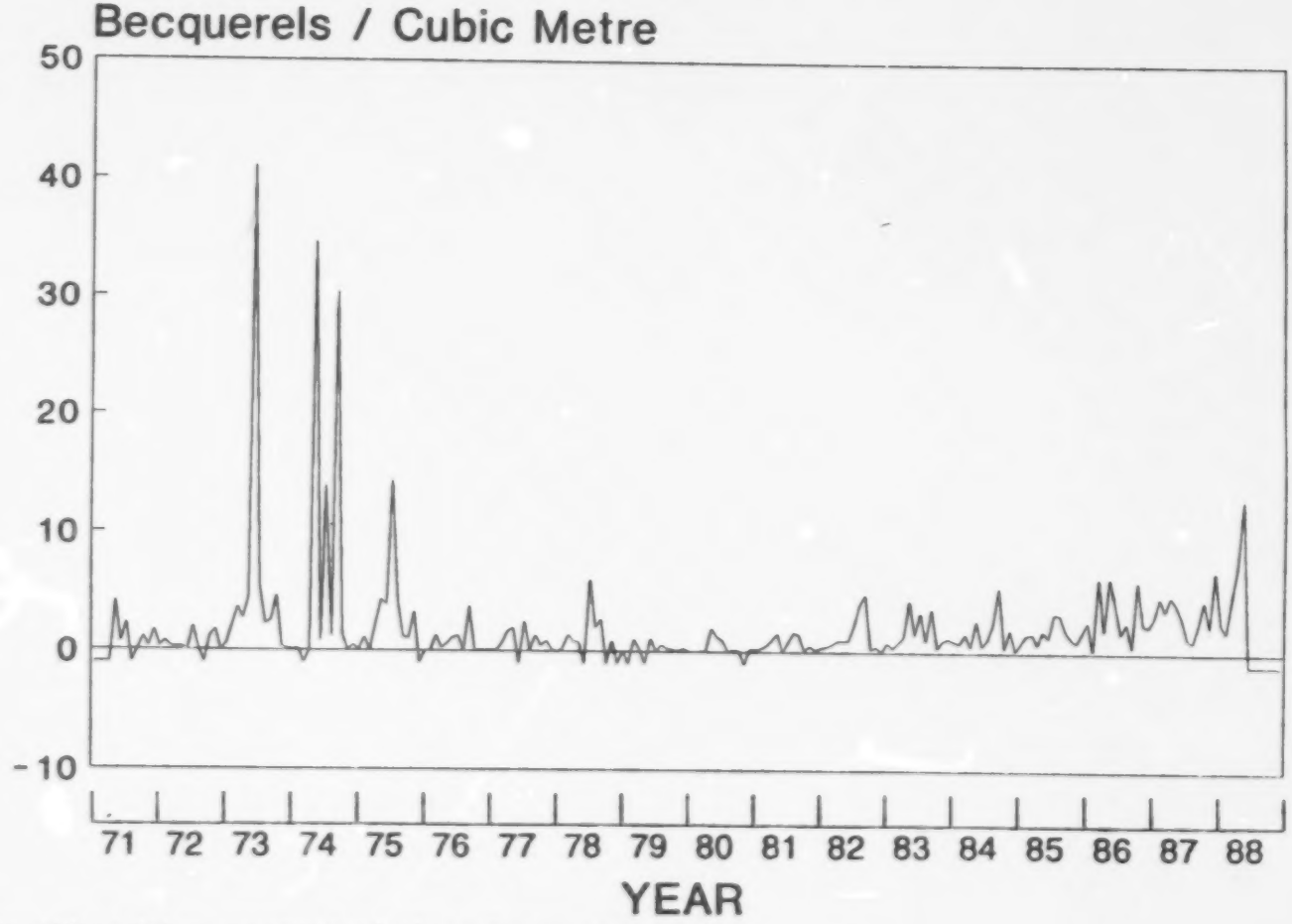
*Monthly tritium content of air water vapour

HEALTH & WELFARE
GROUND MONITORING STATION #1



Monthly tritium content of air water vapour
• Reading of -1 is missing data

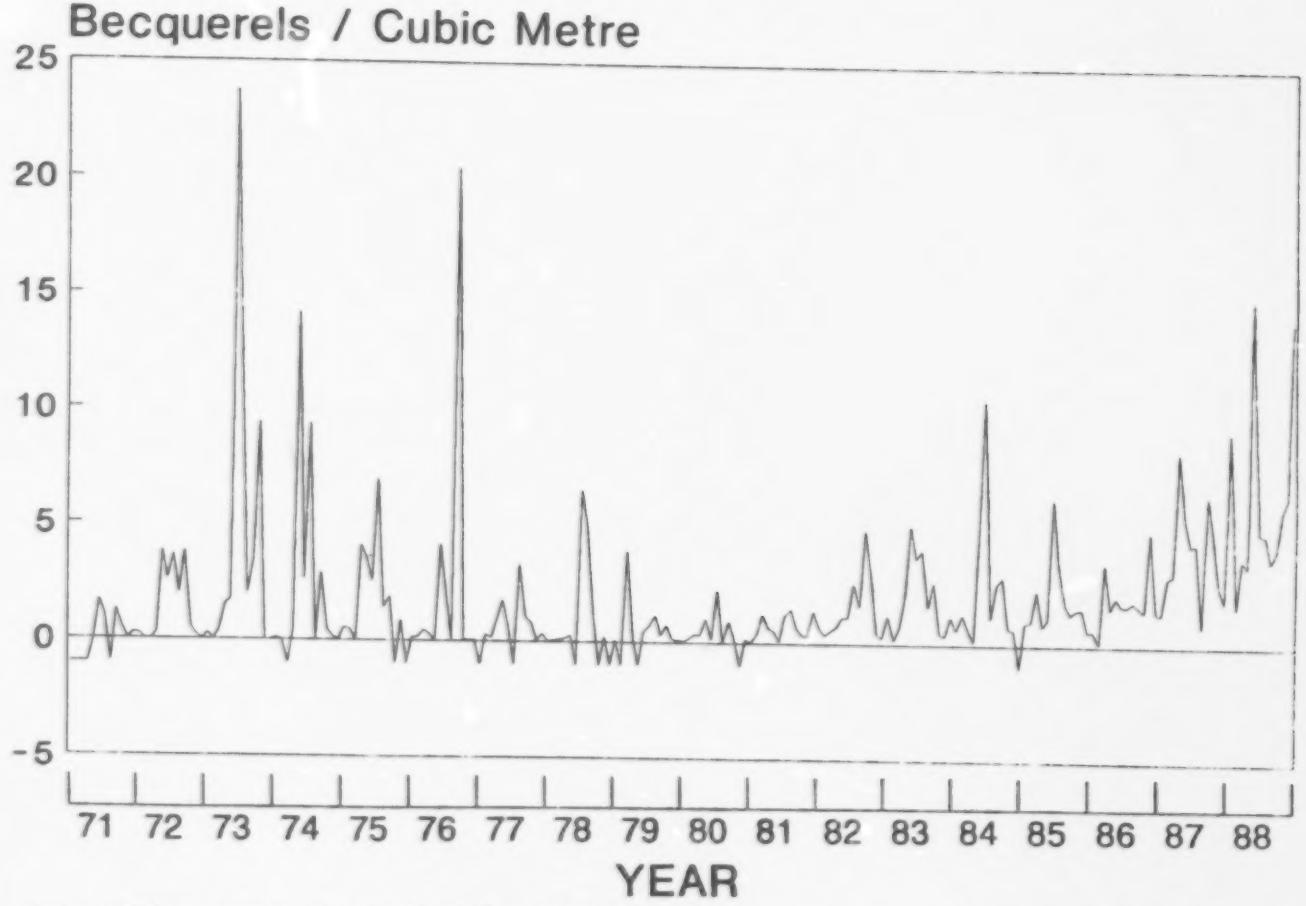
HEALTH & WELFARE
GROUND MONITORING STATION #2



Monthly tritium content of air water vapour
• Reading of -1 is missing data

F4

HEALTH & WELFARE
GROUND MONITORING STATION #3

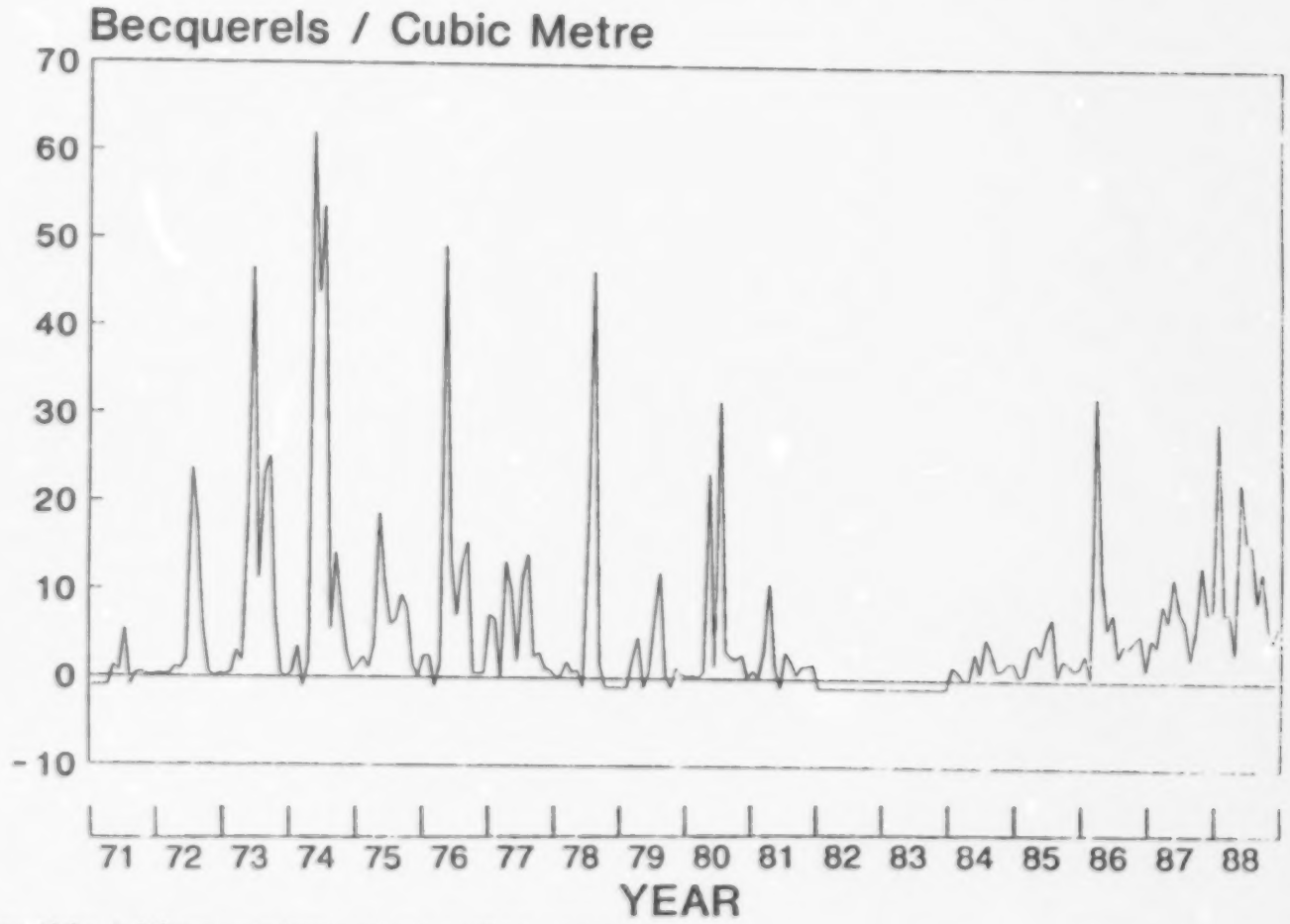


Monthly tritium content of air water vapour

• Reading of -1 is missing data

P5

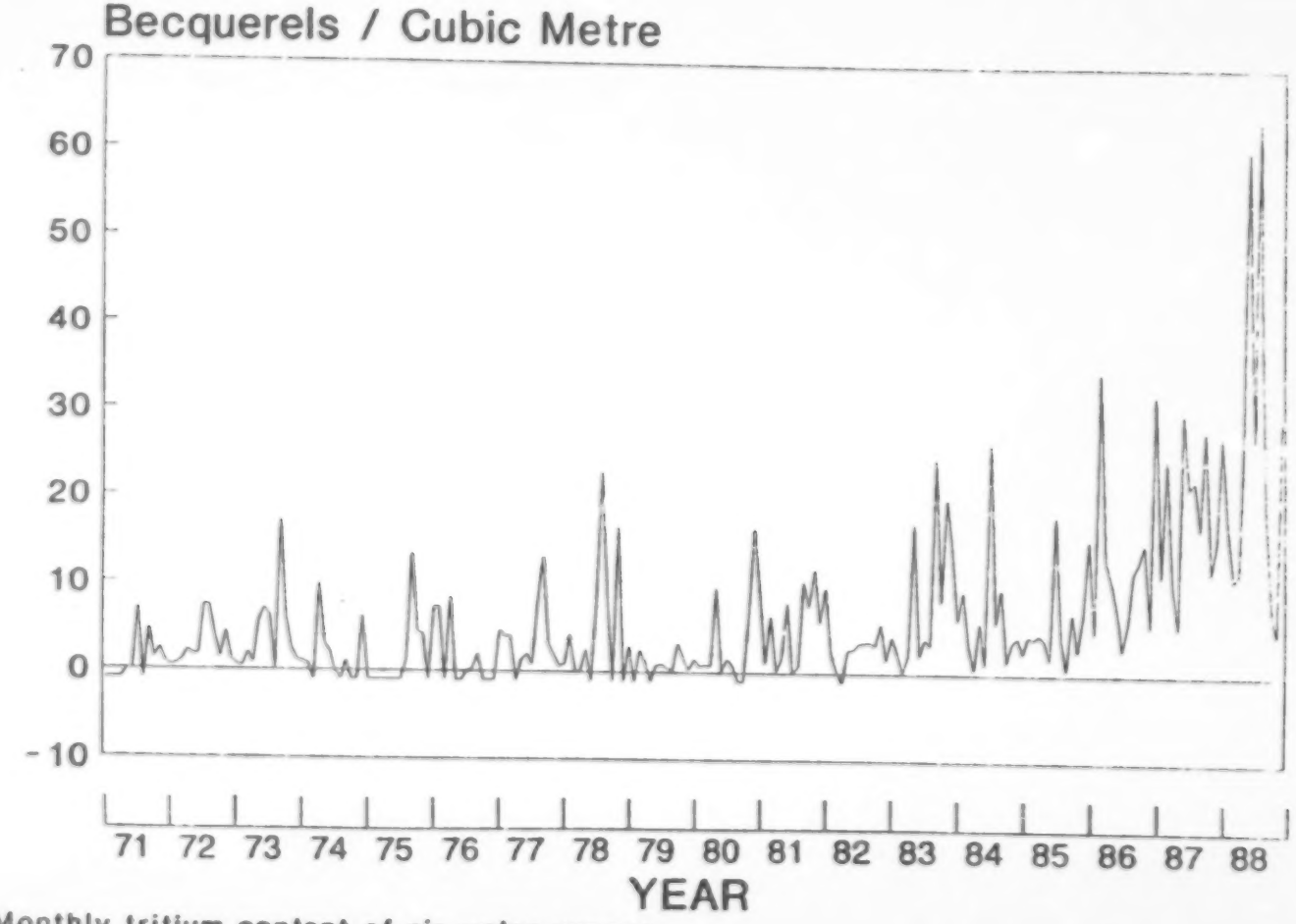
HEALTH & WELFARE
GROUND MONITORING STATION #4



Monthly tritium content of air water vapour

• Reading of -1 is missing data

HEALTH & WELFARE
GROUND MONITORING STATION #5



Monthly tritium content of air water vapour
• Reading of -1 is missing data

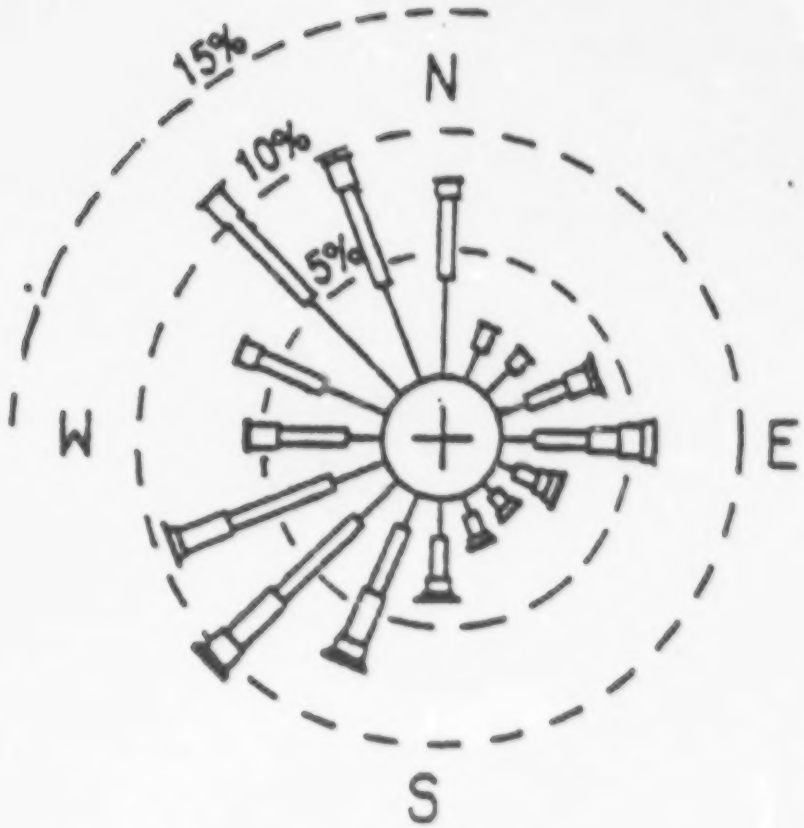
Table . Cross-Correlations for Health and Welfare Tritium Monitoring

	HW1**	HW2	HW3	HW4	HW5	HW6	HW7	HW1-5	HW1-3
AIR*	0.16	0.18	0.28	0.26	0.10	0.02	0.06	0.23	0.21
HW1		0.67	0.57	0.49	0.19	0.06	0.02	0.71	
HW2			0.63	0.54	0.09	0.03	0.04	0.74	
HW3				0.52	0.25	0.10	0.06	0.68	
HW4					0.22	0.30	0.08	0.77	
HW5						0.01	0.11	0.38	
HW6									
HW7									

* Tritium releases from the Pickering NGS "A" and "B" combined

** Tritium monitoring by Health and Welfare at 7 locations near the Pickering NGS

LAKE ONTARIO - PICKERING NGS
WIND ROSE HISTOGRAM
10 m Height
1988 JAN 01 to 1988 DEC 31



LEGEND

SPEED
KM/H

0.0 - 9.9	
10.0 - 19.9	
20.0 - 29.9	
30.0 - 39.9	
40.0 - 49.9	
50.0 - 59.9	
60.0 - 69.9	

DIRECTION - "COMING FROM"

Reproduced courtesy of:
Ontario Hydro
Design and Construction Branch
Geotechnical and Hydraulic Engineering

APPENDIX G

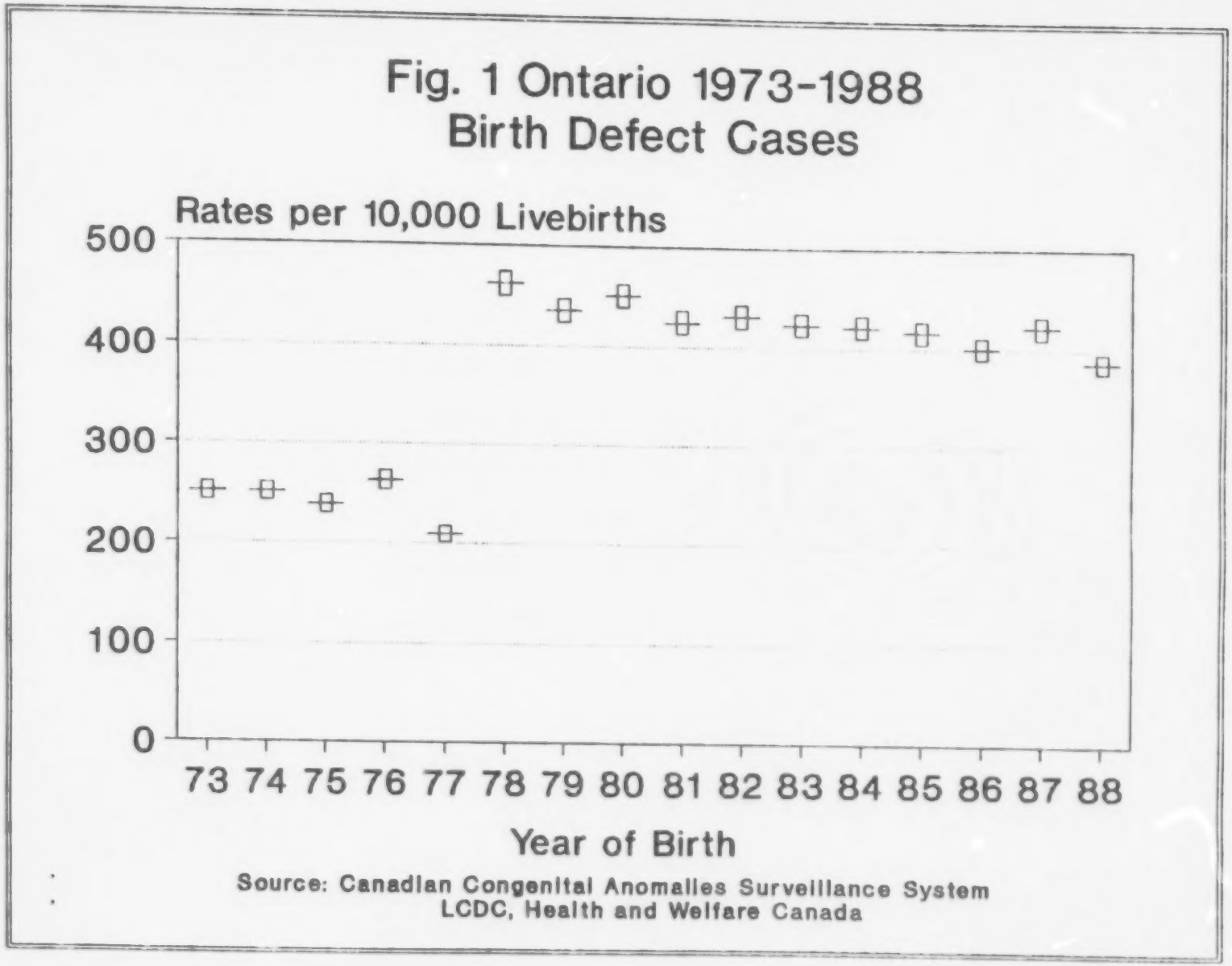
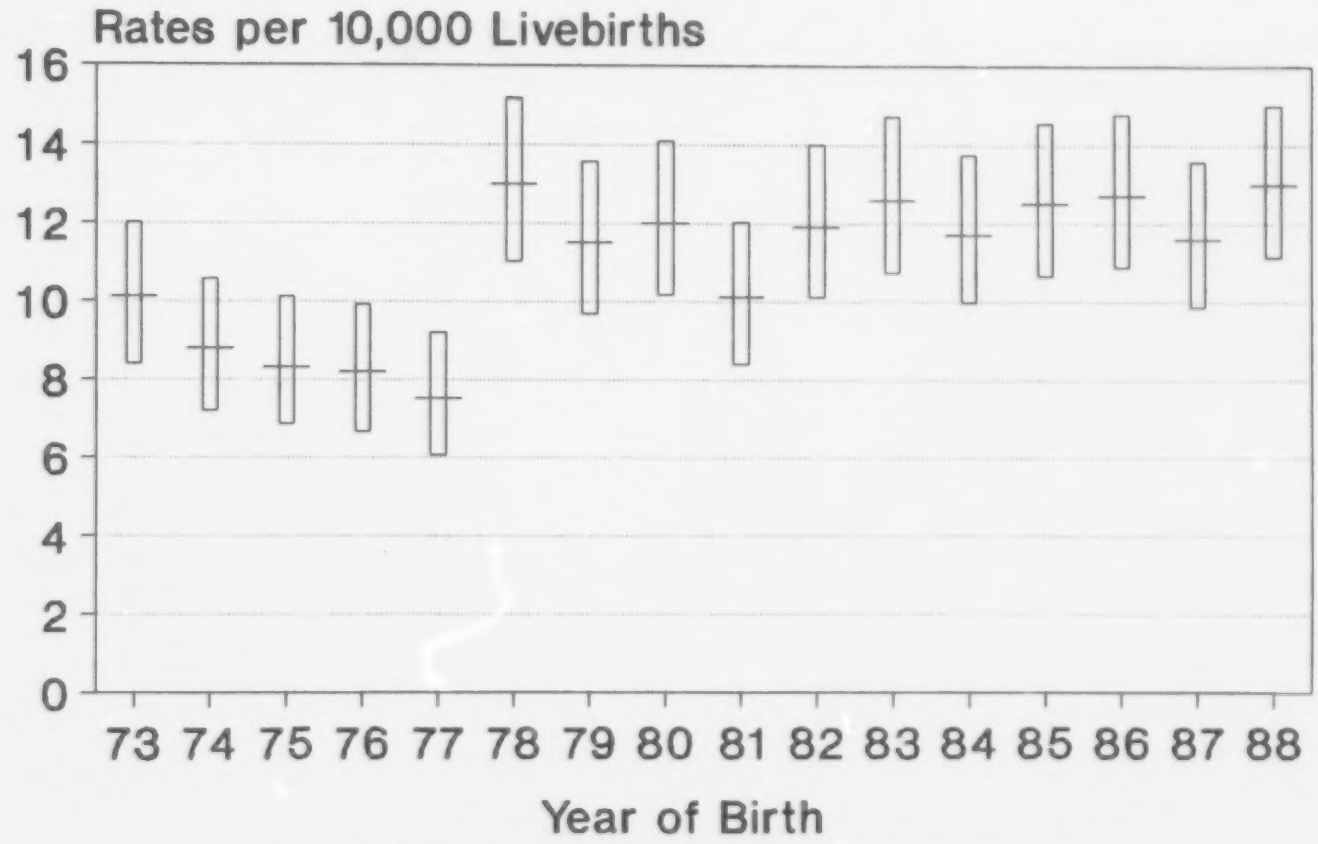


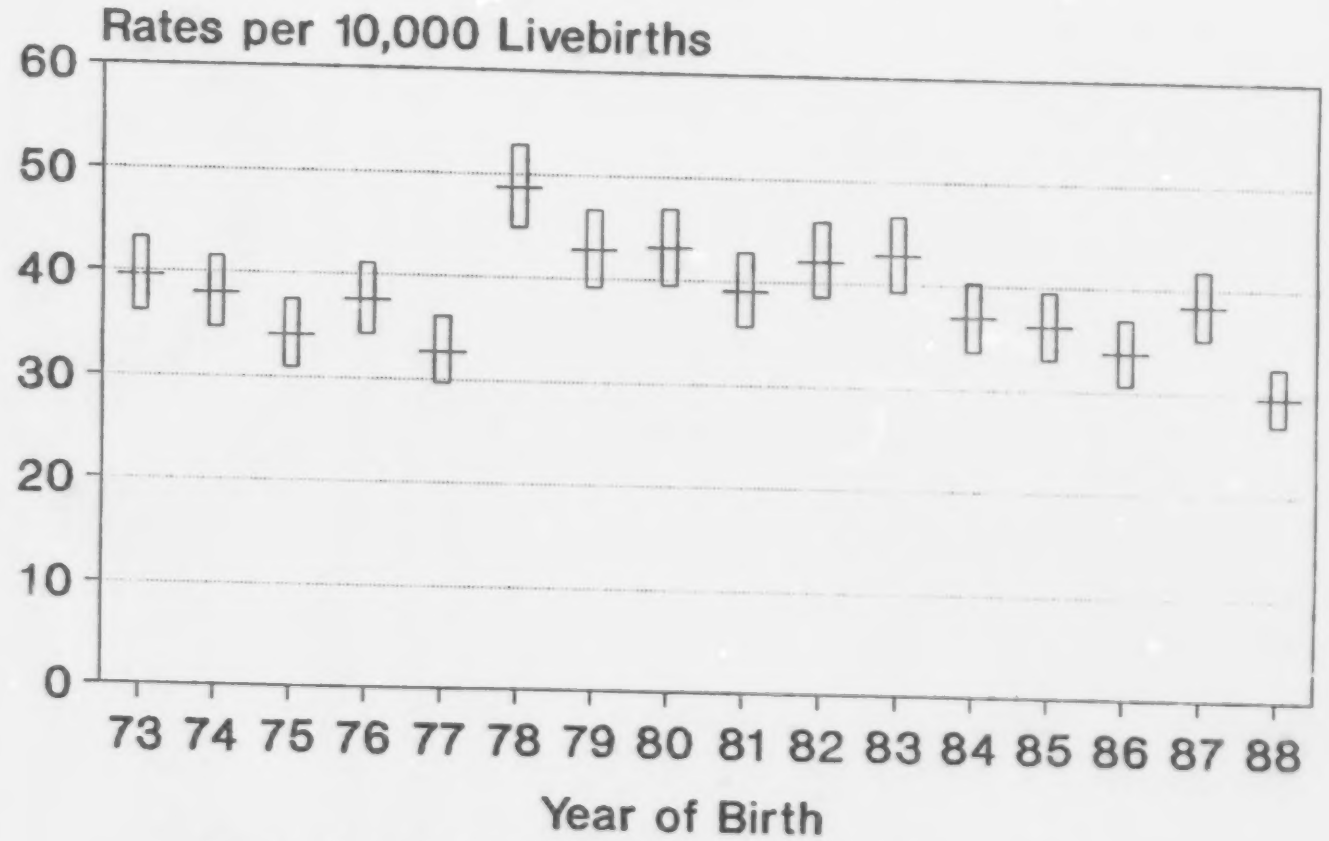
Fig. 1 Ontario 1973-1988
Birth Defect Cases
Rates per 10,000 Livebirths
500
400
300
200
100
0
73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88
Year of Birth
Source: Canadian Congenital Anomalies Surveillance System
LCDC, Health and Welfare Canada

Fig. 3 Ontario 1973-1988
Down Syndrome



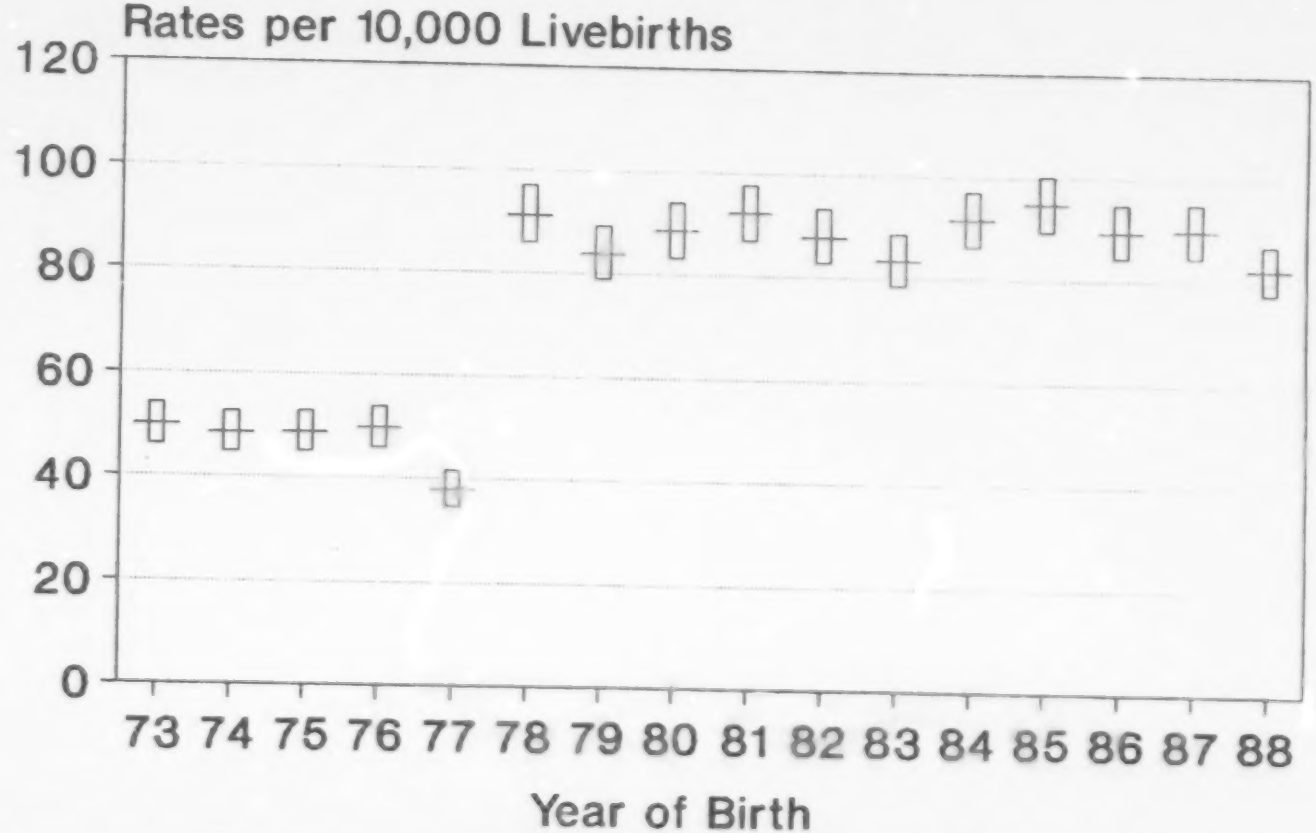
Source: Canadian Congenital Anomalies Surveillance System
LCDC, Health and Welfare Canada

Fig. 4 Ontario 1973-1988
Central Nervous System



Source: Canadian Congenital Anomalies Surveillance System
LCDC, Health and Welfare Canada

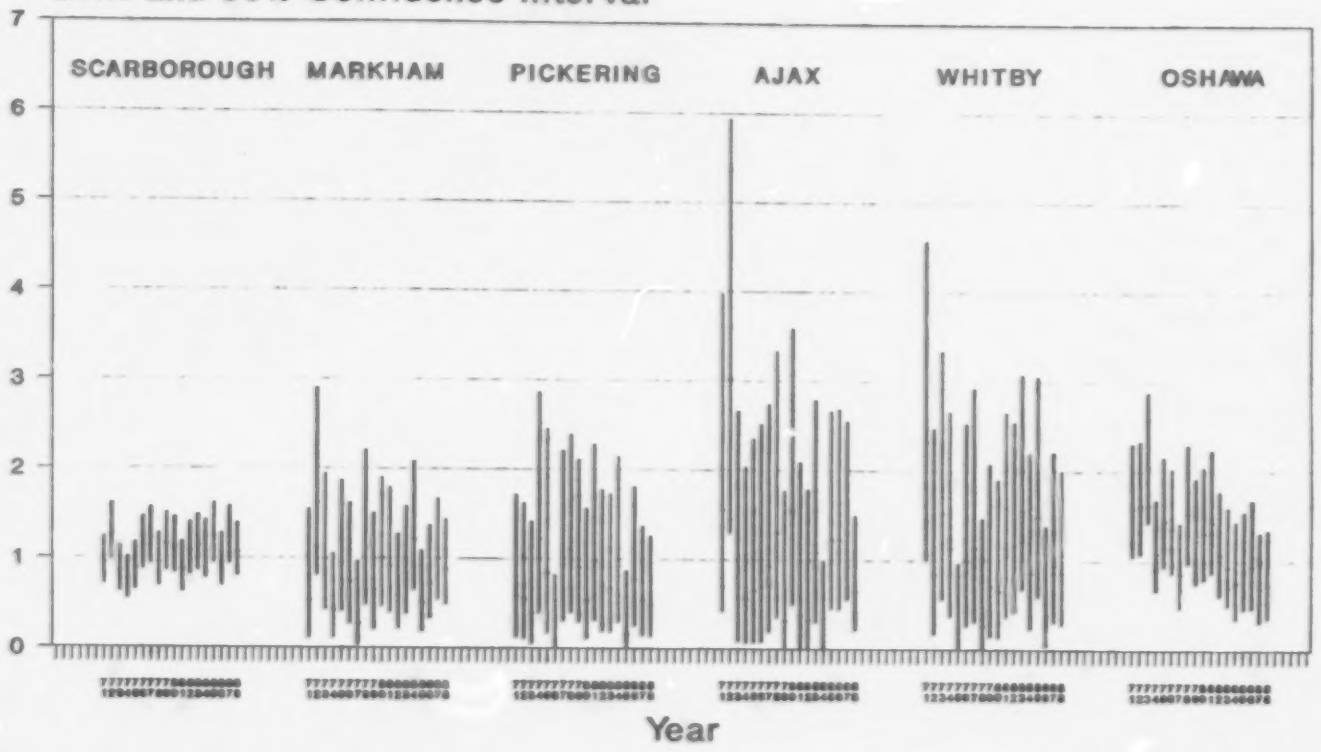
Fig. 5 Ontario 1973-1988
Congenital Heart Defects



Source: Canadian Congenital Anomalies Surveillance System
LCDC, Health and Welfare Canada

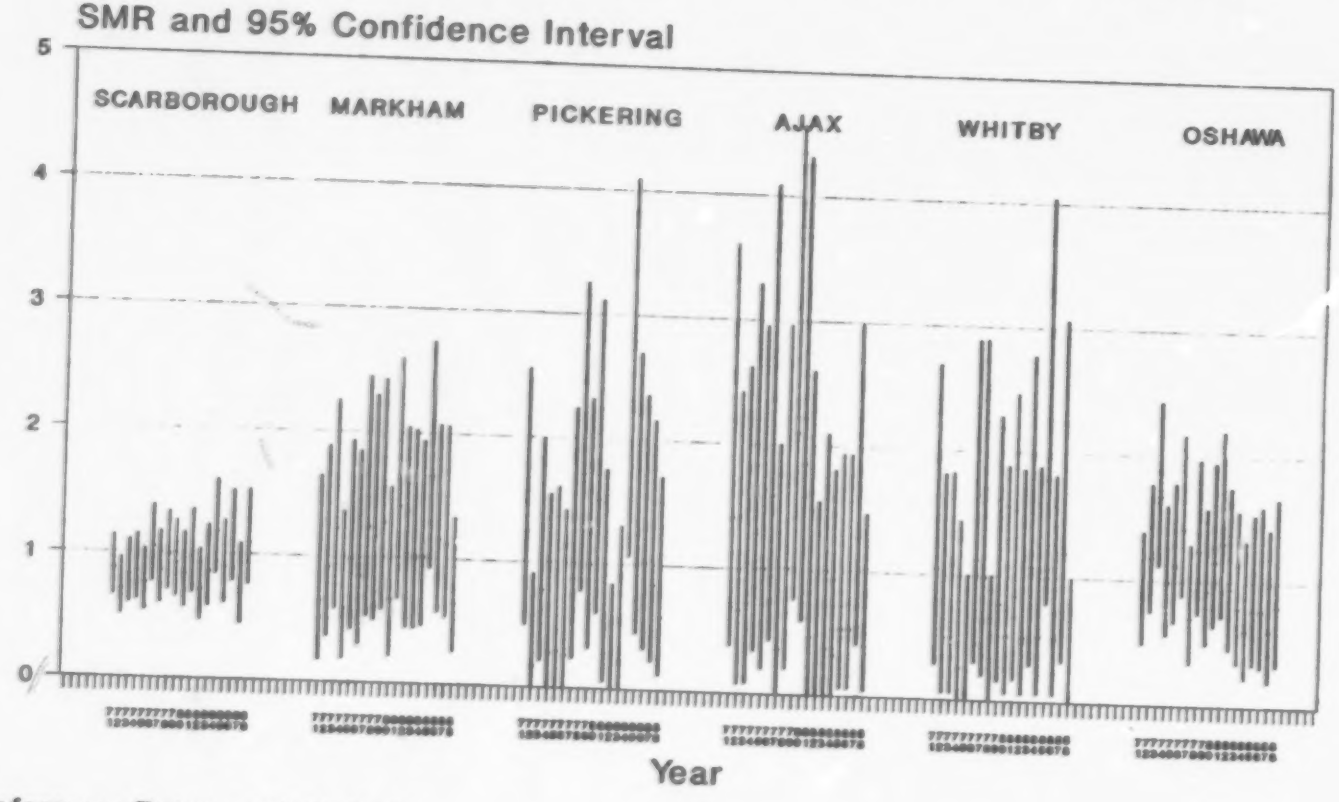
APPENDIX H

Fig. 1.1 - Stillbirth SMRs for Pickering and Adjacent Areas 1971-1988



Reference Rates : All Ontario
SMR - Standardized Mortality Ratio

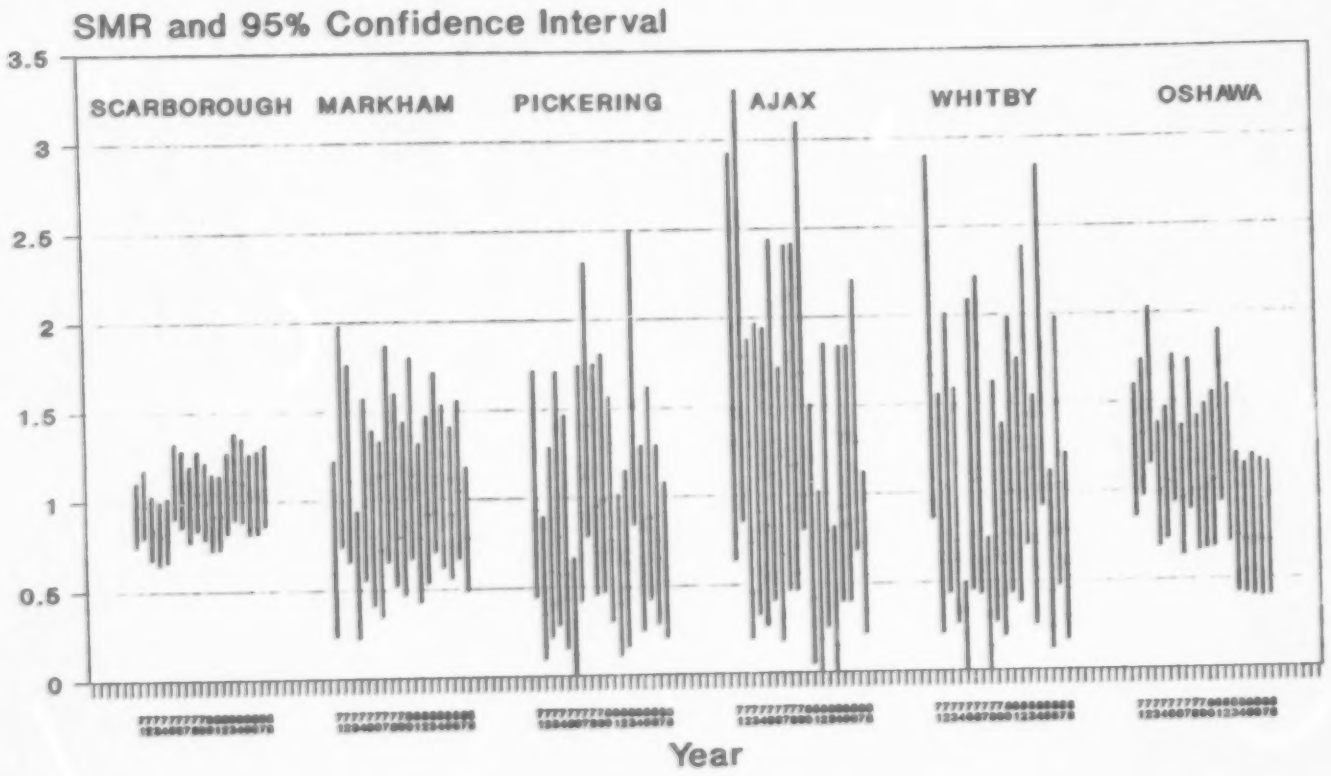
Fig. 1.2 - Neonatal SMRs for Pickering and Adjacent Areas 1971-1988



Reference Rates : All Ontario
SMR - Standardized Mortality Ratio

R2

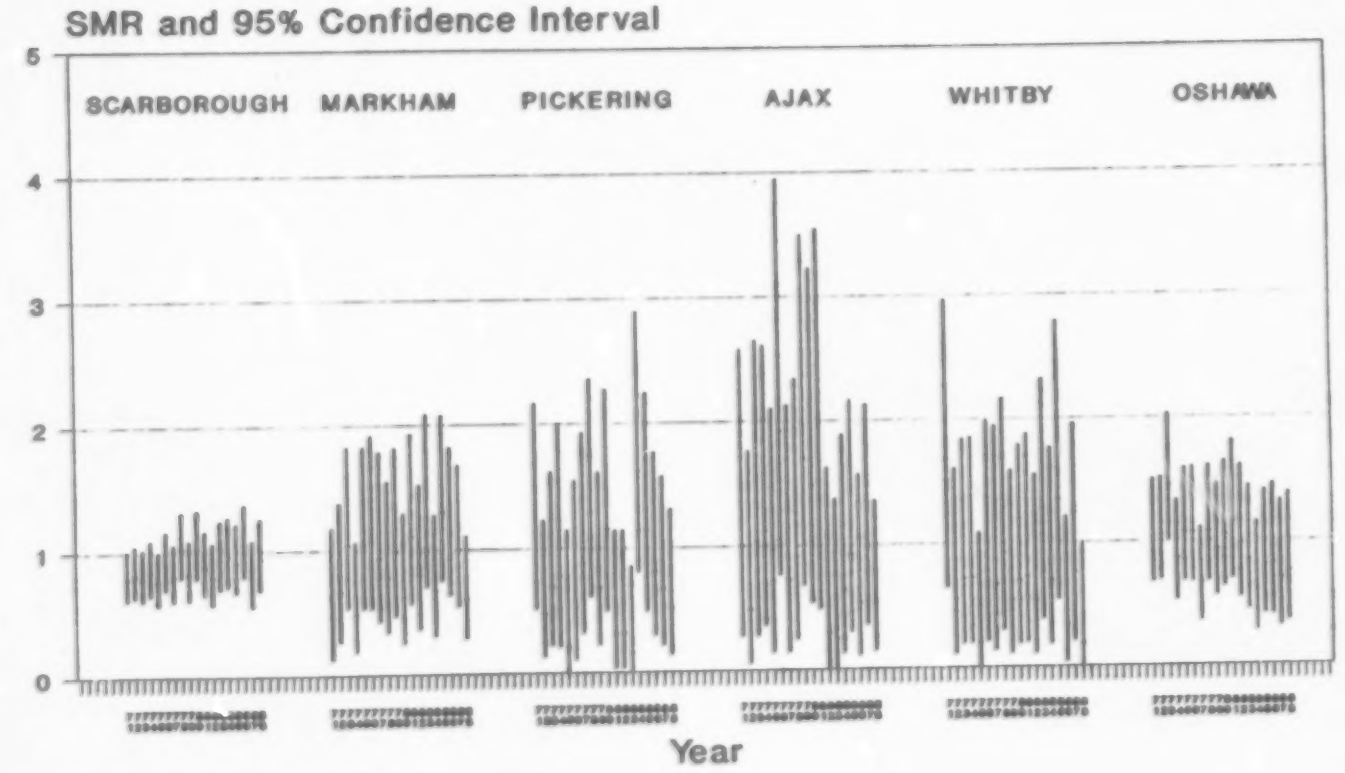
Fig. 1.3 -Stillbirth + Neonatal SMRs for Pickering and Adjacent Areas 1971-1988



Reference Rates : All Ontario
SMR - Standardized Mortality Ratio

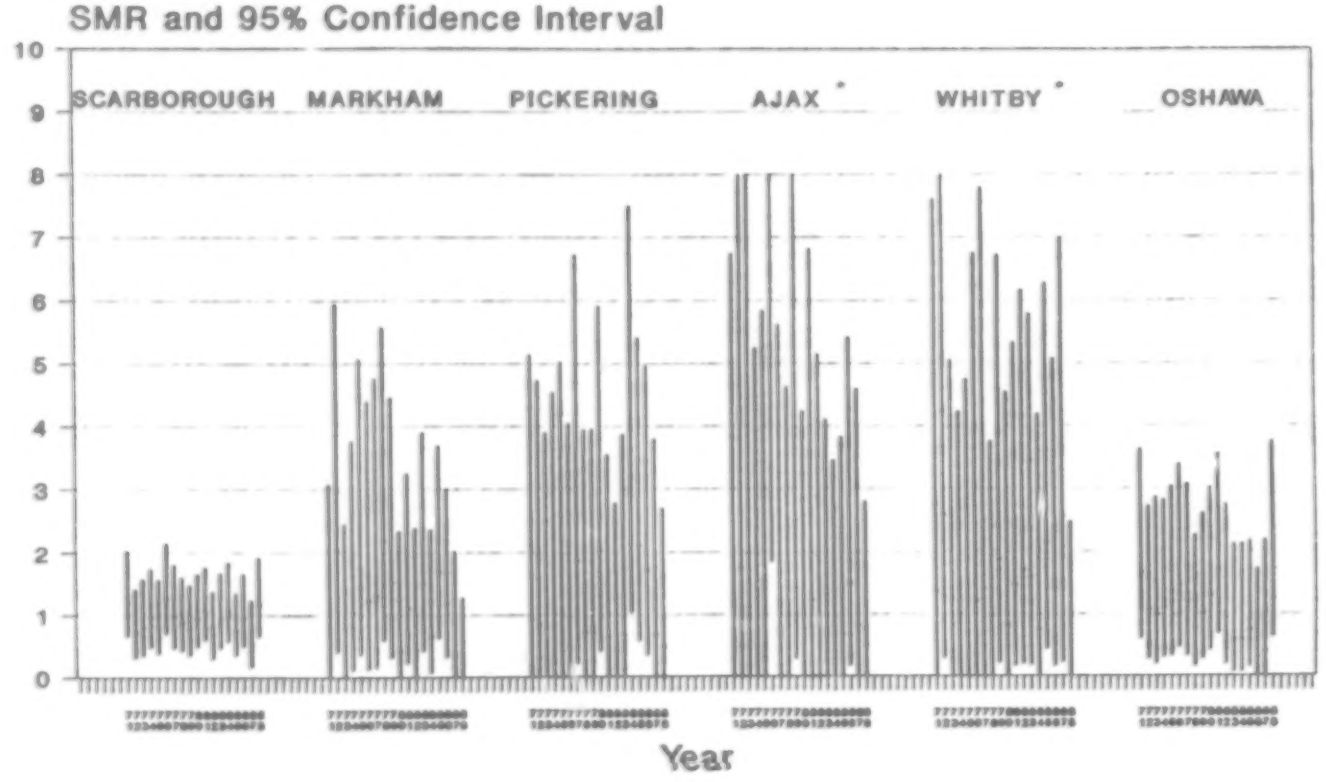
R3

Fig. 1.4 - Infant SMRs for Pickering and Adjacent Areas 1971-1988



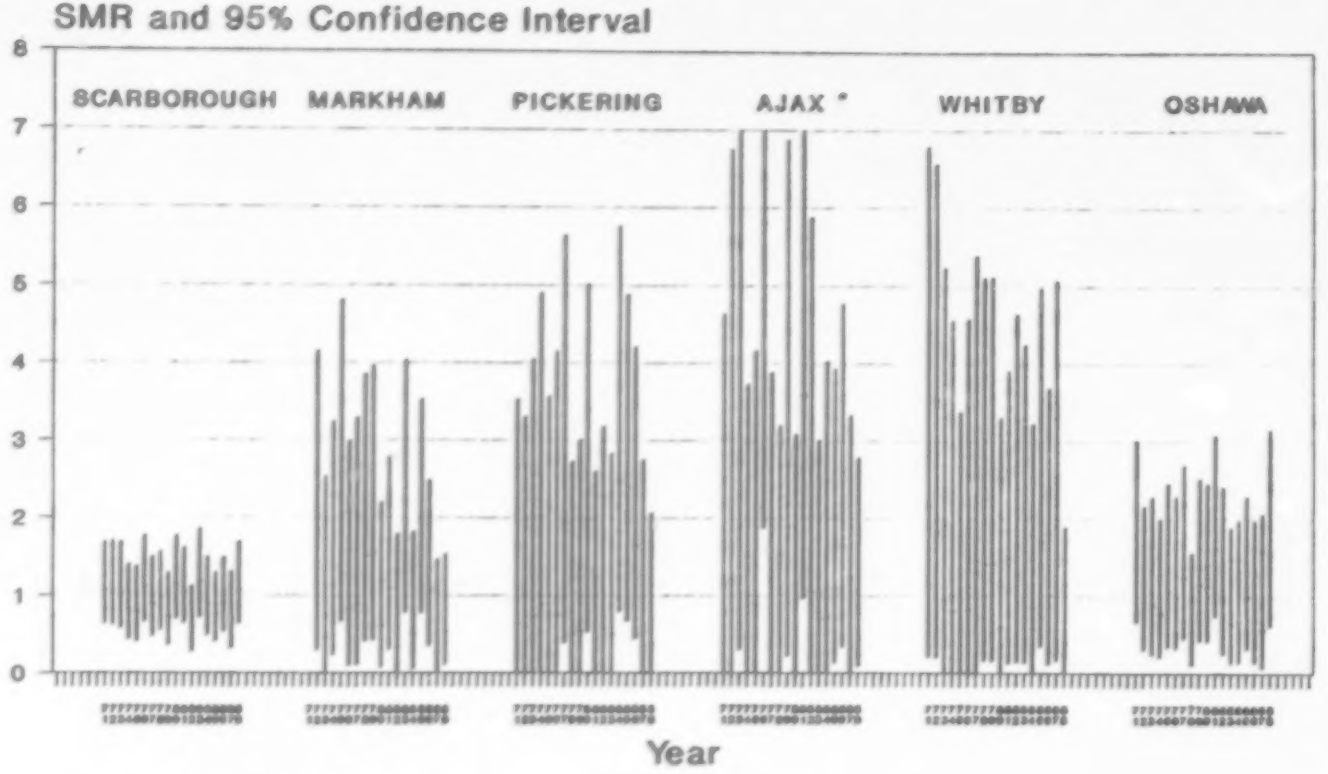
Reference Rates : All Ontario
SMR - Standardized Mortality Ratio

Fig. 1.5-Neonatal Birth Defect SMRs for Pickering and Adjacent Areas 1971-1988



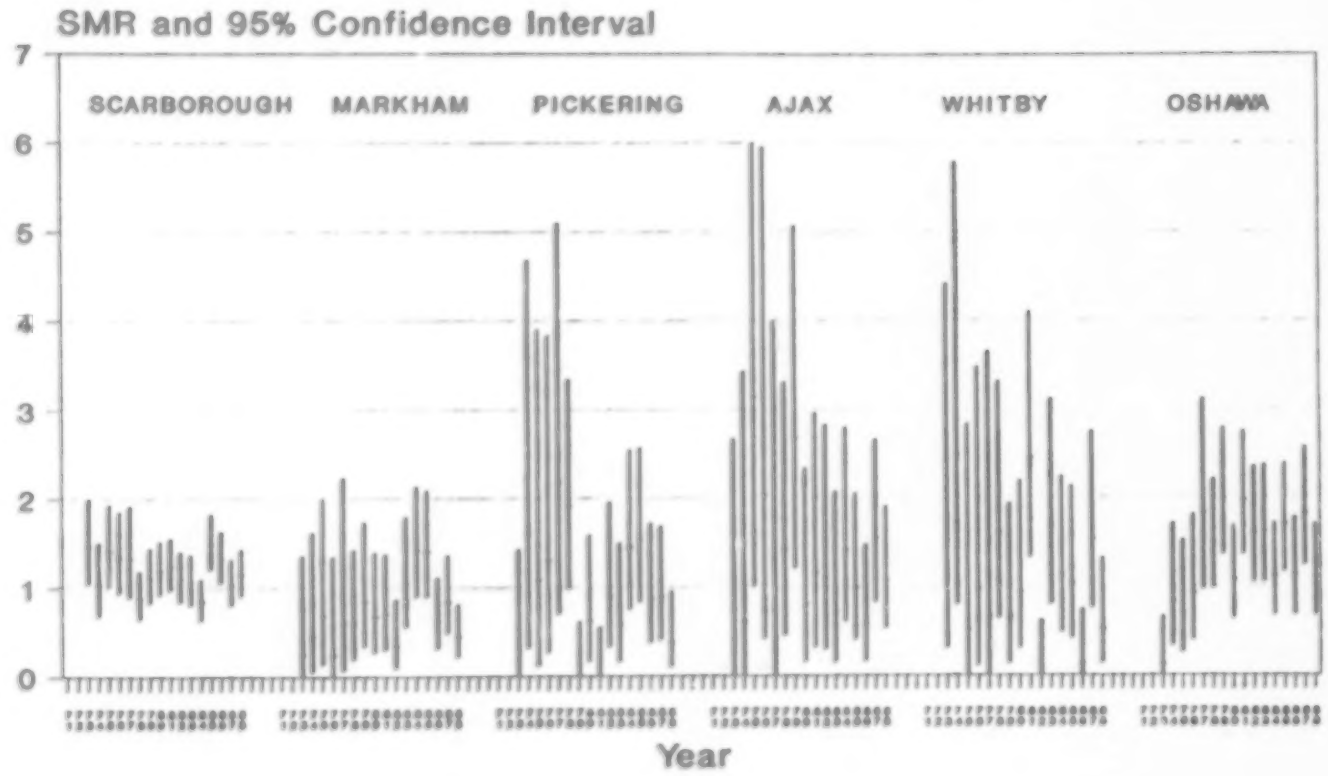
Reference Rates : All Ontario
SMR - Standardized Mortality Ratio
* Upper limit truncated to 8

Fig. 1.6 - Infant Birth Defect SMRs for Pickering and Adjacent Areas 1971-1988



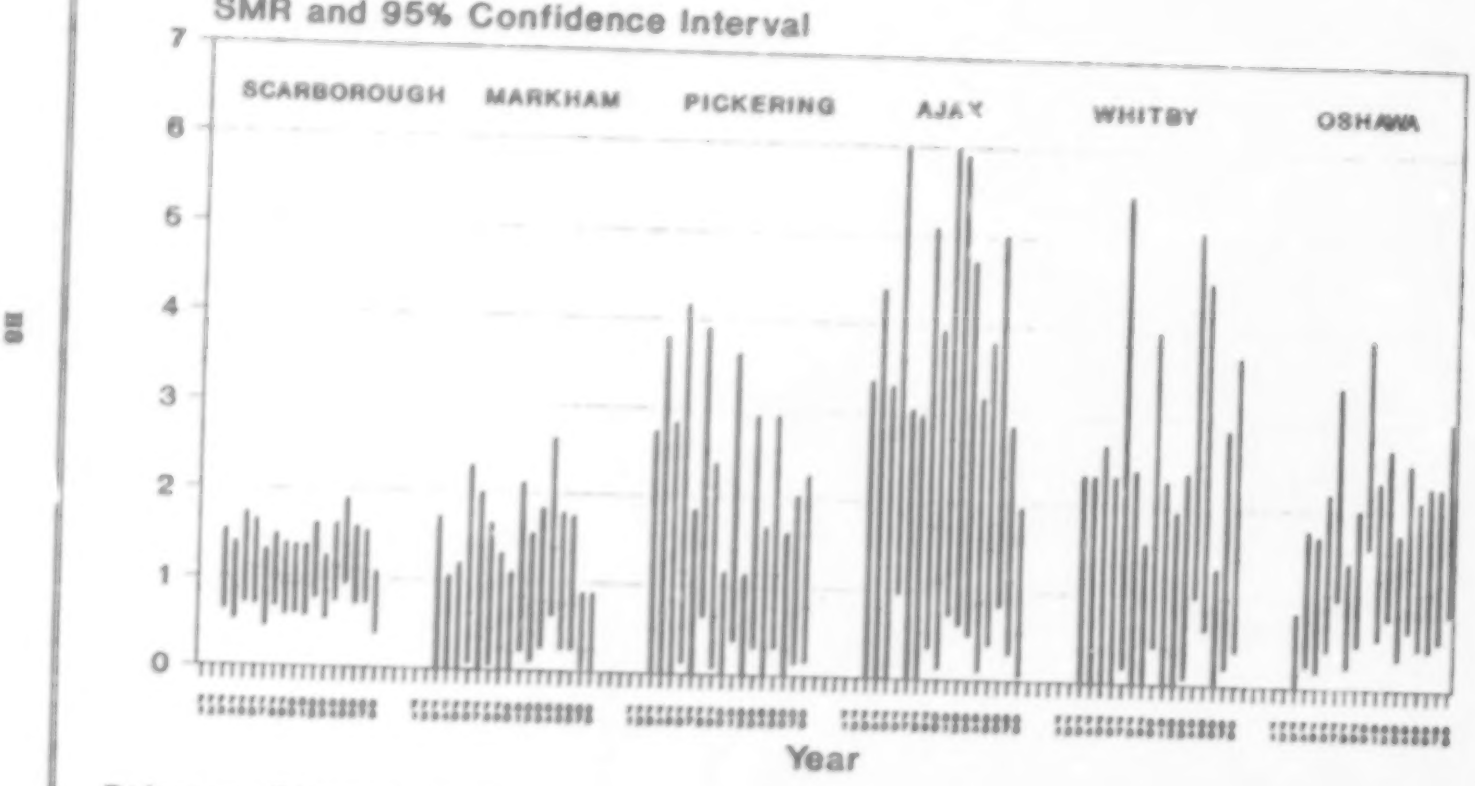
Reference Rates : All Ontario
SMR - Standardized Mortality Ratio
* Upper limit truncated to 7

Congenital Heart Defects SMRs for Pickering and Adjacent Areas 1973-1988



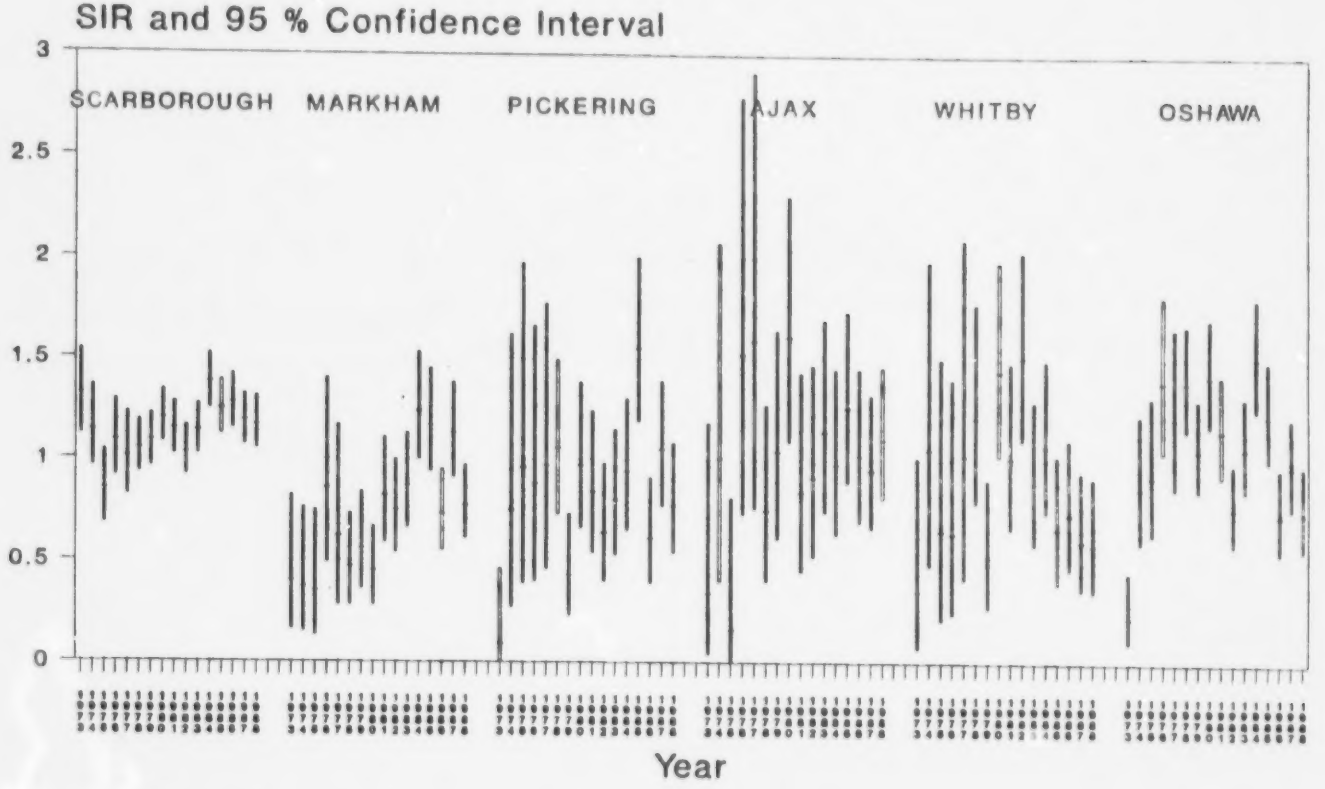
Reference Rates : All Ontario
SMR - Standardized Mortality Ratio
Upper Limit Truncated to 6

Central Nervous System SMRs for Pickering and Adjacent Areas 1973-1988



Reference Rates : All Ontario
SMR - Standardized Mortality Ratio
Upper Limit Truncated to 6

All Anomalies - CNS - CHD
Pickering and Adjacent Areas 1973-1988



Reference Rates : All Ontario
SIR - Standardized Incidence Ratio

APPENDIX I

TABLE 8.
STANDARDIZED BIRTH PREVALENCE RATIOS FOR DOWN SYNDROME, PICKERING AND NEARBY AREA (1973–1988)
REFERENCE = ONTARIO

			CONFIDENCE INTERVAL				RATE/10,000
	YEAR	OBS/EXP	95% LOWER	95% UPPER	OBSERVED	EXPECTED *	BIRTHS
SCARBOROUGH	1973	1.74	0.84	3.20	10	5.7	18
	1974	1.42	0.81	2.79	8	5.6	15
	1975	0.85	0.27	1.98	5	5.9	9
	1976	1.54	0.70	2.92	9	5.8	16
	1977	0.50	0.10	1.43	3	6.0	5
	1978	1.25	0.54	2.46	8	6.4	14
	1979	1.20	0.52	2.36	8	6.6	14
	1980	1.40	0.67	2.57	10	7.1	16
	1981	1.35	0.65	2.48	10	7.4	15
	1982	1.05	0.45	2.07	8	7.6	12
	1983	1.97	1.10	3.24	15	7.6	22
	1984	0.88	0.35	1.80	7	8.0	10
	1985	0.63	0.20	1.46	5	7.9	7
	1986	1.67	0.91	2.79	14	8.4	19
	1987	0.72	0.26	1.56	6	8.3	8
	1988	1.29	0.64	2.31	11	8.5	15
MARKHAM	1973	1.05	0.01	5.32	1	0.9	12
	1974	0.00	0.00	0.26	0	1.1	0
	1975	0.00	0.00	0.27	0	1.0	0
	1976	0.00	0.00	0.29	0	1.0	0
	1977	0.00	0.00	0.28	0	1.0	0
	1978	1.21	0.02	6.11	1	0.8	16
	1979	1.09	0.01	5.51	1	0.9	15
	1980	0.92	0.01	4.64	1	1.1	12
	1981	0.00	0.00	0.24	0	1.2	0
	1982	0.80	0.01	4.05	1	1.2	11
	1983	0.00	0.00	0.20	0	1.4	0
	1984	1.22	0.14	4.26	2	1.6	16
	1985	1.19	0.13	4.15	2	1.7	16
	1986	1.64	0.33	4.70	3	1.8	22
	1987	1.51	0.30	4.34	3	2.0	20
	1988	1.28	0.26	3.67	3	2.3	17
PICKERING	1973	1.81	0.02	9.14	1	0.6	19
	1974	7.19	1.44	20.62	3	0.4	77
	1975	0.00	0.00	0.68	0	0.4	0
	1976	0.00	0.00	0.57	0	0.5	0
	1977	1.54	0.02	7.76	1	0.7	17
	1978	2.65	0.30	9.25	2	0.8	32
	1979	0.00	0.00	0.38	0	0.7	0
	1980	2.53	0.28	8.81	2	0.8	31
	1981	2.62	0.29	9.12	2	0.8	32
	1982	1.22	0.02	6.18	1	0.8	15
	1983	1.15	0.01	5.80	1	0.9	14
	1984	2.10	0.24	7.32	2	1.0	26
	1985	3.75	1.01	9.50	4	1.1	46
	1986	0.00	0.00	0.25	0	1.1	0
	1987	3.23	0.87	8.18	4	1.2	39
	1988	0.76	0.01	3.82	1	1.3	9
AJAX	1973	0.00	0.00	0.94	0	0.3	0
	1974	0.00	0.00	0.78	0	0.4	0
	1975	0.00	0.00	0.79	0	0.4	0
	1976	0.00	0.00	0.87	0	0.3	0
	1977	2.53	0.03	12.76	1	0.4	27
	1978	0.00	0.00	0.59	0	0.5	0
	1979	0.00	0.00	0.54	0	0.5	0
	1980	1.93	0.03	9.78	1	0.5	21
	1981	4.41	0.50	15.38	2	0.5	48
	1982	0.00	0.00	0.55	0	0.5	0
	1983	1.63	0.02	8.24	1	0.6	18
	1984	2.75	0.31	9.57	2	0.7	30
	1985	1.20	0.02	6.05	1	0.8	13
	1986	2.21	0.25	7.72	2	0.9	24
	1987	0.97	0.01	4.88	1	1.0	11
	1988	2.32	0.47	6.65	3	1.3	25

TABLE 8. (cont'd)
STANDARDIZED BIRTH PREVALENCE RATIOS FOR DOWN SYNDROME, PICKERING AND NEARBY AREA (1973–1988)
REFERENCE = ONTARIO

			CONFIDENCE INTERVAL				RATE/10,000
	YEAR	OBS/EXP	95% LOWER	95% UPPER	OBSERVED	EXPECTED *	BIRTHS
WHITBY	1973	2.32	0.03	11.71	1	0.4	25
	1974	2.23	0.03	11.27	1	0.4	24
	1975	0.00	0.00	0.65	0	0.4	0
	1976	2.21	0.03	11.16	1	0.5	24
	1977	0.00	0.00	0.64	0	0.4	0
	1978	0.00	0.00	0.51	0	0.5	0
	1979	0.00	0.00	0.45	0	0.6	0
	1980	0.00	0.00	0.41	0	0.7	0
	1981	1.40	0.02	7.08	1	0.7	16
	1982	2.57	0.29	8.95	2	0.8	29
	1983	1.23	0.02	6.22	1	0.8	14
	1984	0.00	0.00	0.32	0	0.9	0
	1985	1.22	0.02	6.18	1	0.8	14
	1986	0.00	0.00	0.30	0	0.9	0
	1987	0.00	0.00	0.31	0	0.9	0
	1988	1.02	0.01	5.15	1	1.0	12
OSHAWA	1973	1.65	0.33	4.75	3	1.8	18
	1974	2.67	0.86	6.18	5	1.9	29
	1975	0.53	0.01	2.67	1	1.9	6
	1976	0.53	0.01	2.67	1	1.9	6
	1977	0.98	0.11	3.43	2	2.0	11
	1978	0.00	0.00	0.13	0	2.2	0
	1979	1.32	0.27	3.80	3	2.3	15
	1980	1.38	0.28	3.96	3	2.2	16
	1981	0.47	0.01	2.36	1	2.1	5
	1982	1.88	0.51	4.76	4	2.1	21
	1983	1.36	0.27	3.89	3	2.2	15
	1984	0.45	0.01	2.25	1	2.2	5
	1985	0.85	0.10	2.97	2	2.3	10
	1986	0.47	0.01	2.37	1	2.1	5
	1987	2.24	0.72	5.18	5	2.2	26
	1988	0.43	0.01	2.20	1	2.3	5

SUMMARY

SCARBOROUGH	73–88	1.21	1.02	1.43	137	113.0	14
MARKHAM	73–88	0.85	0.51	1.35	18	21.1	11
PICKERING	73–88	1.85	1.19	2.76	24	12.9	22
AJAX	73–88	1.48	0.80	2.44	14	9.6	16
WHITBY	73–88	0.83	0.38	1.57	9	10.9	9
OSHAWA	73–88	1.06	0.74	1.47	36	33.9	12

* Ajusted for Year of Birth and Mother's Age

TABLE 1 CALCULATION OF PREDICTED DOWN SYNDROME CASES FOR ONTARIO

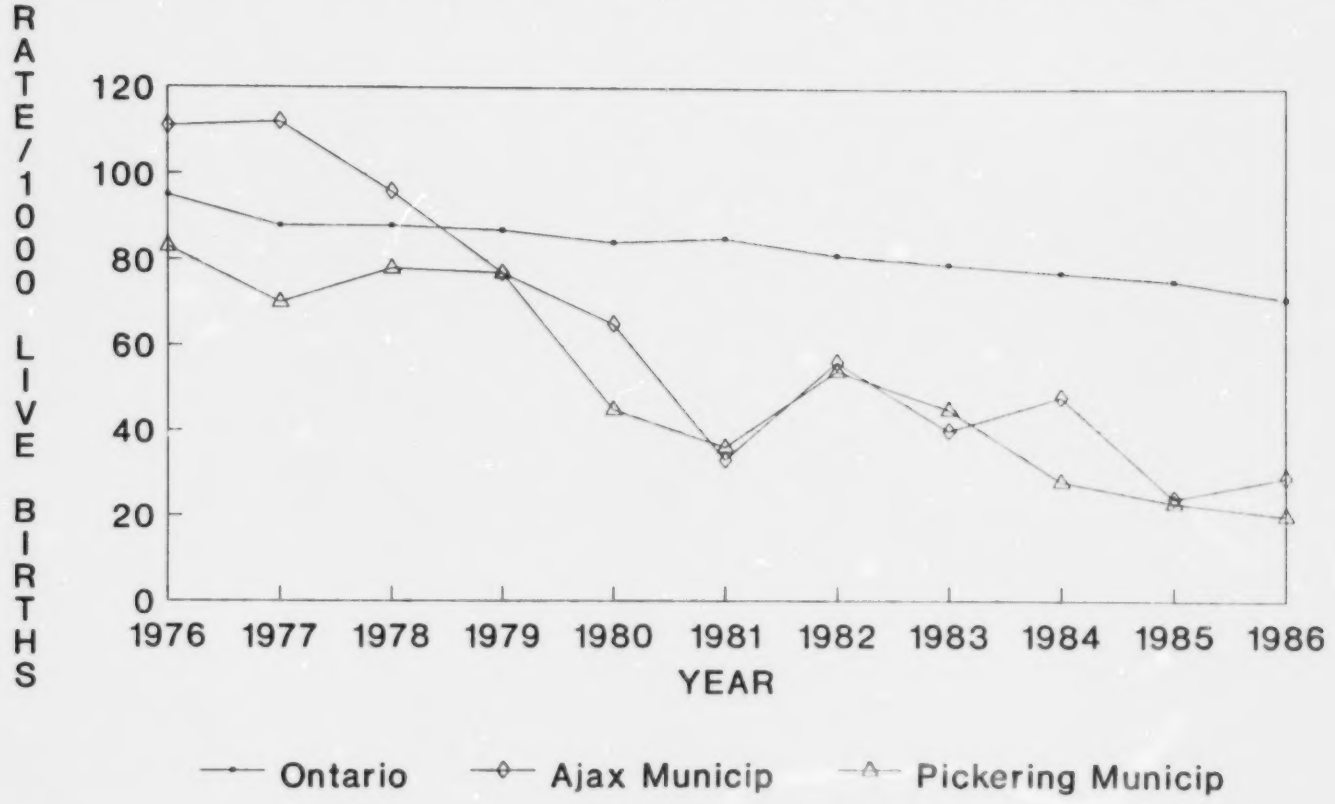
	Age of Mother							Down Syndrome Averages/Year			
	<20	20–24	25–29	30–34	35–39	40–44	45–49	Expected Cases	Expected Rate	Reported Cases	Reported Rate
DOWN SYNDROME RISK* per 1,000 Births	0.74	0.74	0.74	1.33	4.20	15.10	50.00				
LIVEBIRTH DISTRIBUTION**											
Ontario 1975	11.3%	32.8%	36.4%	14.7%	4.0%	0.9%	0.0%				
Ontario 1978	9.5%	31.3%	36.4%	18.0%	4.1%	0.7%	0.0%				
Ontario 1983	6.5%	27.2%	38.3%	21.5%	5.9%	0.6%	0.0%				
Ontario 1988	4.8%	20.5%	39.4%	25.8%	8.4%	1.0%	0.0%				
Ontario 78,83,88	6.8%	26.1%	38.1%	21.9%	6.2%	0.8%	0.0%				
EXPECTED AVERAGE CASES PER YEAR											
Ontario 73–77	10.5	30.5	33.9	24.6	21.3	16.1	0.0	136.9	10.88	107.0	8.60
Ontario 78–88	6.5	24.9	36.4	37.7	33.5	14.5	0.7	154.2	11.97	155.6	12.10

* Data from Hook, E.B., Lindsjo, A., American Journal of Human Genetics, Volume 30, 1978:19–27; Trimble, B.K., Baird, P., American Journal of Medical Genetics, Volume 2, 1978:1–5; and Christianson, R.E., The Lancet, Volume 2, 1976:1198.

** Maternal Age distribution from Vital Statistics Volume 1, Statistics Canada for the years 1975, 1978, 1983, and 1988.

APPENDIX J

SPONTANEOUS ABORTION RATE FOR ONTARIO AND AJAX AND PICKERING MUNICIPALITIES



Source: Compendium of Statistical Tables
Durham, Halton, Northumberland, Ontario
Health Statistics Surveillance System

APPENDIX K

Pickering Area Livebirths, Stillbirths and Infant Deaths 1971–1988

Statistics Canada & HMRI Livebirths

Place	Scarborough	Markham	Pickering			Ajax			Whitby	Oshawa	Ontario
Year	SCan	SCan	HMRI	SCan	% *	HMRI	SCan	% *	SCan	SCan	SCan
1971	5548	570		517			260		349	1718	130,395
1972	5199	687		547			268		358	1750	125,080
1973	5481	817		513			275		396	1887	125,014
1974	5369	913		384			333		413	1727	125,564
1975	5627	895		378			325		400	1750	126,975
1976	5538	833		480			298		418	1747	123,900
1977	5714	950		602			366		400	1875	123,843
1978	5576	896	615	687	89.5%	427	386	110.6%	476	1890	121,879
1979	5807	989	598	707	84.3%	470	402	116.9%	540	1978	122,592
1980	6240	1170	648	729	88.9%	467	425	109.9%	601	1898	124,232
1981	6484	1239	625	721	86.7%	413	375	110.1%	622	1869	123,034
1982	6636	1347	672	761	88.3%	482	412	112.1%	678	1843	125,779
1983	6654	1487	718	816	87.7%	558	507	110.1%	707	1926	127,725
1984	6981	1764	780	900	86.7%	661	615	107.5%	767	1964	132,076
1985	6920	1805	876	966	90.7%	780	742	102.4%	713	2052	133,065
1986	7355	1974	906	1024	88.5%	818	773	105.8%	824	1867	134,712
1987	7272	2121	1017	1128	90.2%	934	931	100.3%	796	1956	135,503
1988	7437	2515	1087	1191	91.3%	1176	1145	102.7%	856	2013	138,961
Total 78–88	73342	17307	8538	9630	88.7%	7146	6713	106.5%	7580	21253	1,419,558
Total 71–88	111796	22872	8538	13031		7146	8836		10314	33485	2,300,312

Stillbirths

Place	Scarborough	Markham	Pickering	Ajax	Whitby	Oshawa	Ontario
Year							
1971	52	3	3	4	8	26	1,304
1972	65	11	3	8	3	25	1,251
1973	46	8	2	2	6	23	1,238
1974	43	4	5	2	5	18	1,335
1975	47	8	3	2	0	16	1,200
1976	61	6	0	2	4	20	1,203
1977	61	2	5	3	4	19	1,086
1978	39	0	6	4	1	19	915
1979	44	2	6	4	1	15	937
1980	48	5	4	4	3	15	916
1981	38	3	5	0	5	11	851
1982	52	2	2	1	7	25	923
1983	53	4	2	3	7	19	899
1984	46	5	5	1	3	11	780
1985	55	6	2	5	6	12	857
1986	43	5	6	4	2	9	830
1987	59	12	3	9	4	9	886
1988	48	11	4	3	6	10	895
Total	900	97	66	61	75	302	18,306

Infant Deaths

Place	Scarborough	Markham	Pickering	Ajax	Whitby	Oshawa	Ontario
Year							
1971	67	4	9	4	8	27	1,990
1972	65	7	4	2	3	26	1,908
1973	61	12	5	4	4	34	1,740
1974	61	6	4	5	4	20	1,666
1975	75	12	1	3	1	24	1,614
1976	62	11	3	7	4	23	1,515
1977	52	9	6	3	3	14	1,384
1978	65	8	10	4	5	23	1,373
1979	49	10	5	7	3	19	1,247
1980	61	7	8	8	4	19	1,175
1981	50	12	2	5	4	19	1,073
1982	44	9	2	1	3	15	1,041
1983	50	15	1	1	6	13	1,013
1984	51	9	11	3	4	9	992
1985	48	17	8	5	7	12	981
1986	56	16	8	3	2	11	969
1987	38	14	5	8	4	9	886
1988	48	10	4	4	1	10	910
Total	979	188	94	73	70	329	23,458

* HMRI livebirth count as a percentage of Stats Canada livebirth count

APPENDIX L

Appendix L: Comments and Partial Re-Analysis of McArthur's Report

This appendix contains a short re-analysis of some of the data on newborn infant mortality focused on by David McArthur in his report entitled "Fatal Birth Defects, Newborn Infant Fatalities and Tritium Emissions in the Town of Pickering, Ontario: A Preliminary Examination". Although the main body of our report addresses the question in a systematic way, we thought it would still be useful to present further analysis here.

We have seen a combined review of McArthur's report by the Ontario Ministry of Health and the Durham Regional Health Unit[1] and agree with the comments made in their review. We will not duplicate their comments here, but rather present a few further observations about one of the described associations.

Neonatal Infant Death Rates and Waterborne Tritium Releases

Figure 1 presents neonatal infant death rates and 95% confidence intervals for the Municipality of Pickering for the period 1971-1988. (Figure 1.2 in Appendix H of the main report presents the same neonatal data only expressed as ratios with Ontario rates as reference.) Superimposed on these data are waterborne tritium releases and neonatal death rates for Ontario for the same period. The confidence intervals include the all Ontario rate in every year except 1984 suggesting that the rates were not unexpectedly high in Pickering in any year except 1984.

In Figure 2 waterborne tritium release is plotted against the newborn infant death rate in Pickering by year. The filled squares represent the data points available to McArthur for his report. Some inklings of a correlation are evident from the tendency for the years with higher releases to be associated with higher newborn infant mortality rates. However, when the 1971-1973 and 1986-1988 data (unfilled squares) are added the correlation completely disappears.

These data suggest that:

1) neonatal mortality rates in Pickering fluctuate markedly from year to year. This amount of fluctuation is expected with such small numbers of outcomes.

2) Only in 1984 is the neonatal infant death rate elevated such that the 95% confidence interval for the rate does not include the rate for Ontario. One would expect a rate this high by chance alone once in every 20 years. The years 1983 and 1984 were a period of low to average airborne and waterborne tritium releases.

3) It is known that misclassification between stillbirth and neonatal death can occur. When these two categories are combined for Pickering for 1984, the relative risk for the two outcomes combined and compared to Ontario is only 1.5, and not unexpectedly high (See Appendix H - Figure 1.3).

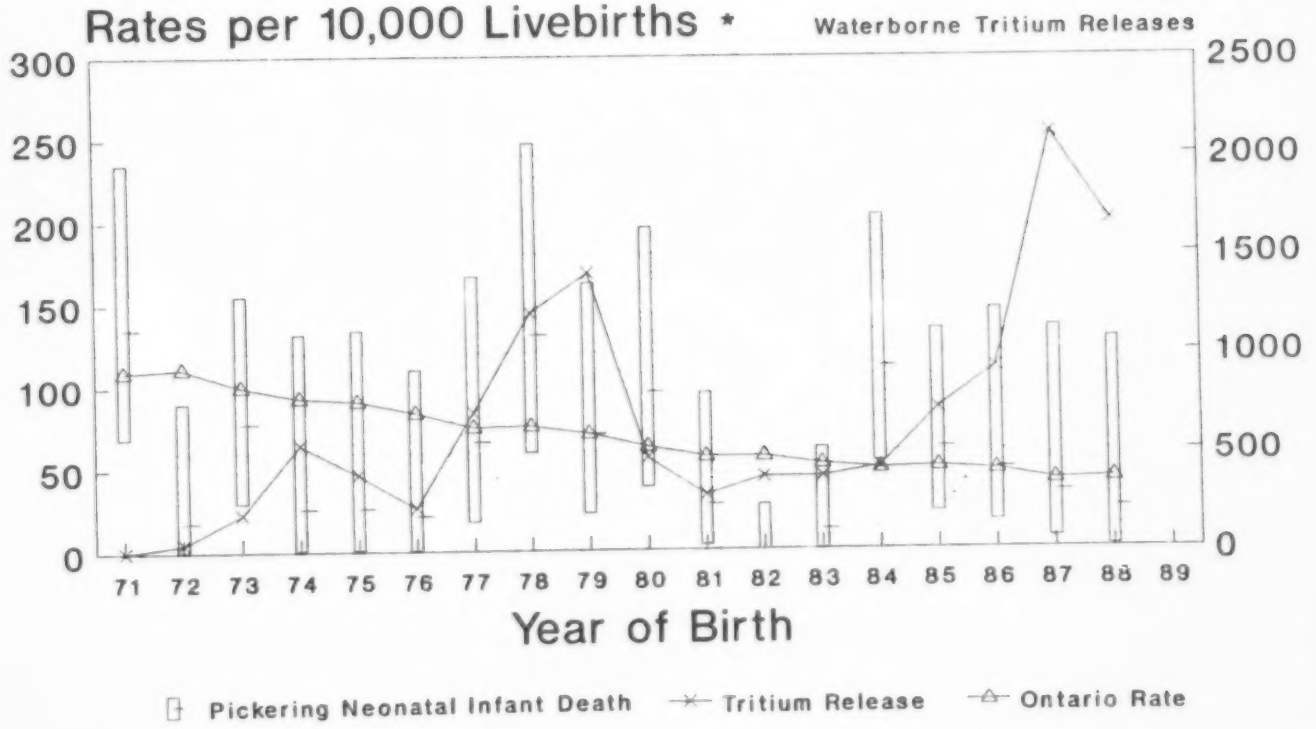
4) If waterborne tritium resulted in a problem in Pickering in 1984 one would expect to see similar problems in that year in Ajax and Whitby which share common water supplies after the Fall of 1980. Relative risks for these two communities, however, are not elevated. (see Appendix H - Figure 1.3).

5) If accumulation of tritium until a threshold was reached were resulting in a problem, one would not expect to see increased risk isolated in one year.

REFERENCE

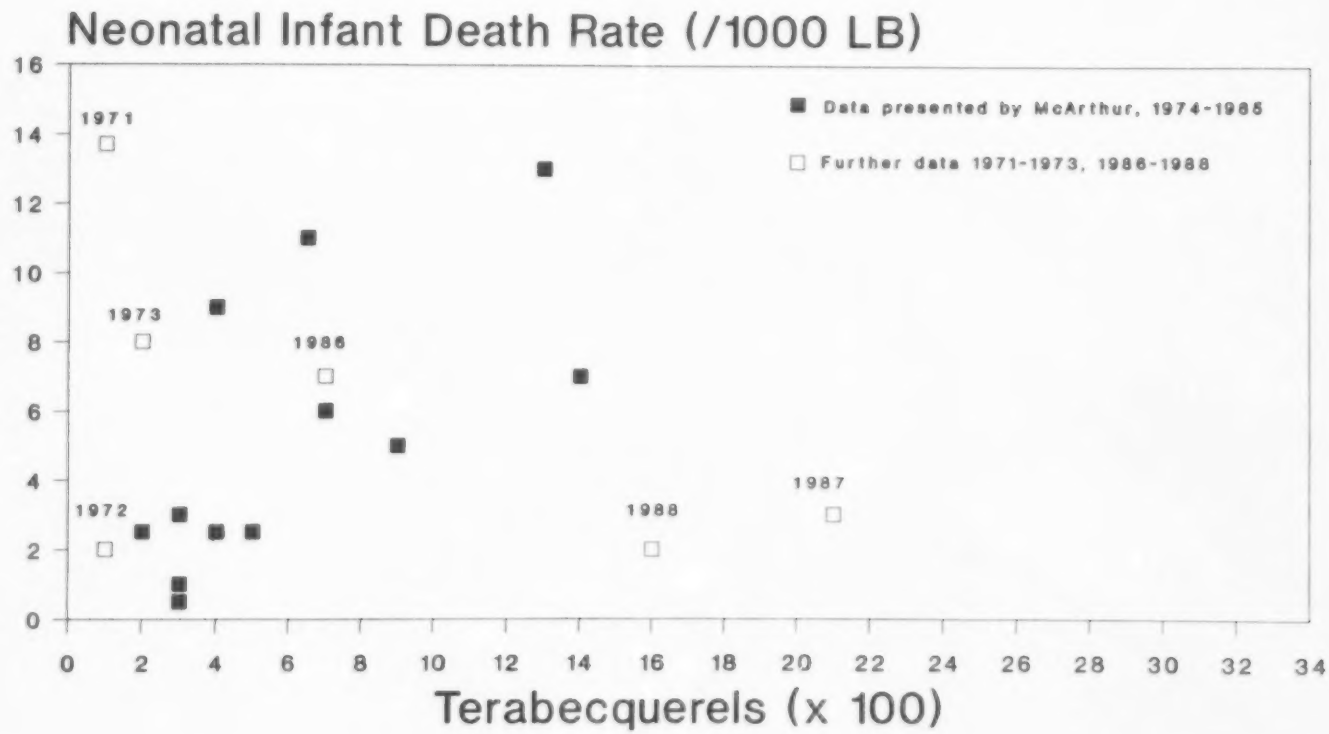
1. Unpublished Internal Report "A Combined Review of McArthur Report by Ontario Ministry of Health & Durham Regional Health, February 7, 1989".

Figure 1
PICKERING NEONATAL INFANT DEATH RATES AND WATERBORNE TRITIUM RELEASES



* Vertical Bars = 95% Confidence Intervals

Figure 2 Yearly Tritium Release from Pickering NGS vs Pickering Newborn Infant Death Rate 1971-1988



Source: Canadian Congenital Anomalies Surveillance System
LCDC, Health and Welfare Canada